



US005922022A

United States Patent [19]

[11] Patent Number: **5,922,022**

Nash et al.

[45] Date of Patent: **Jul. 13, 1999**

[54] **BIFURCATED CONNECTOR SYSTEM FOR CORONARY BYPASS GRAFTS AND METHODS OF USE**

[75] Inventors: **John E. Nash; Douglas G. Evans**, both of Downingtown, Pa.

[73] Assignee: **Kensey Nash Corporation**, Exton, Pa.

[21] Appl. No.: **09/002,267**

[22] Filed: **Dec. 31, 1997**

4,854,318 8/1989 Solem et al. .
 4,930,502 6/1990 Chen .
 4,931,057 6/1990 Cummings et al. .
 4,957,499 9/1990 Lipatov et al. .
 5,123,908 6/1992 Chen .
 5,156,619 10/1992 Ehrenheld .
 5,192,289 3/1993 Jessen .
 5,222,963 6/1993 Brinkerhoff et al. .
 5,250,058 10/1993 Miller et al. .
 5,330,490 7/1994 Wilk et al. .
 5,346,501 9/1994 Regula et al. .
 5,364,389 11/1994 Anderson .
 5,399,352 3/1995 Hanson .
 5,425,738 6/1995 Gustafson et al. .

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/923,682, Sep. 4, 1997.

[51] **Int. Cl.⁶** **A61F 2/06**
 [52] **U.S. Cl.** **623/1; 623/12**
 [58] **Field of Search** **623/1, 11, 12; 128/898**

(List continued on next page.)

Primary Examiner—Michael J. Milano
Attorney, Agent, or Firm—Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.

[56] References Cited

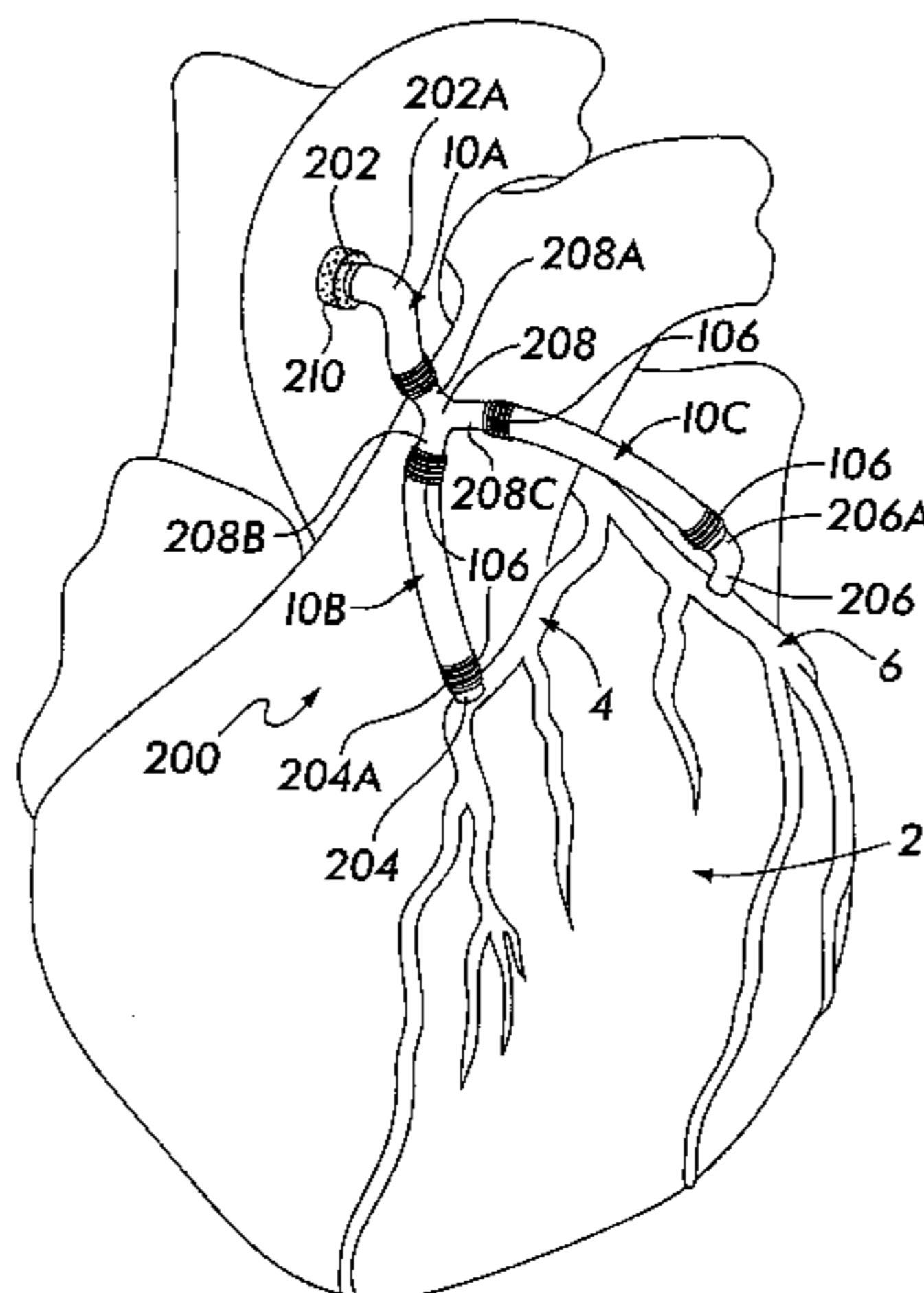
U.S. PATENT DOCUMENTS

2,127,903 8/1938 Bowen .
 3,029,819 4/1962 Starks 623/1
 3,096,560 7/1963 Liebig 623/1
 3,155,095 11/1964 Brown .
 3,588,920 6/1971 Wesolowski .
 3,620,218 11/1971 Schmitt et al. .
 3,683,926 8/1972 Suzuki .
 4,214,586 7/1980 Mericle .
 4,233,981 11/1980 Schomacher .
 4,366,819 1/1983 Kaster .
 4,368,736 1/1983 Kaster .
 4,470,415 9/1984 Wozniak .
 4,501,263 2/1985 Harbuck .
 4,512,761 4/1985 Raible .
 4,552,148 11/1985 Hardy, Jr. et al. .
 4,601,718 7/1986 Possis 623/1
 4,610,661 9/1986 Possis 623/1
 4,675,008 6/1987 Tretbar .
 4,721,109 1/1988 Healey .
 4,753,236 6/1988 Healey .
 4,769,029 9/1988 Patel .
 4,816,028 3/1989 Kapadia et al. .
 4,851,001 7/1989 Taheri .

[57] ABSTRACT

A system and method of use for effecting the bypass or other anastomosis of a portion of a native blood vessel, duct, lumen or other tubular organ within the body of a living being. The system includes a connector assembly and a deployment instrument for carrying the device to the desired position within the vessel, duct, lumen or tubular organ. The system includes a piercer-dilator instrument to form an opening in the wall of the vessel, duct, lumen or tubular organ into which the connector assembly is deployed by the deployment instrument. The connector assembly is at least partially formed of a resorbable material and includes movable members for securing it to the tissue of the vessel, duct, lumen or tubular organ contiguous with the opening. Other components may be included in the device for expediting the anastomosis procedure, with or without the use of sutures. Moreover, the system can be used to bypass of at least two coronary arteries by a common connection with the aorta utilizing at least two bypass grafts, a single upstream anastomosis connector, a pair of downstream anastomosis connectors, and a common bifurcated midstream anastomosis connector, for securement between the aorta and the coronary arteries.

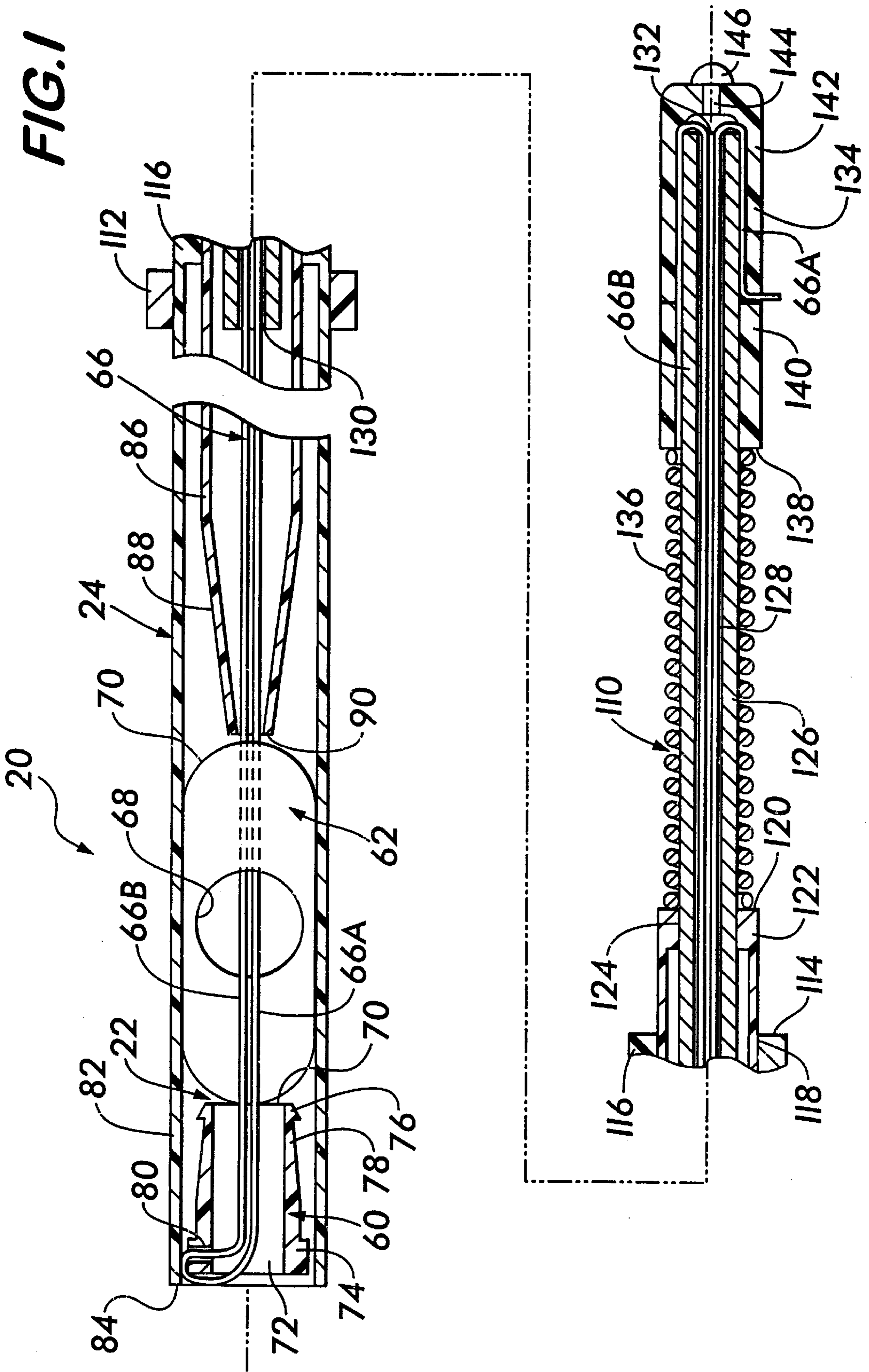
31 Claims, 7 Drawing Sheets

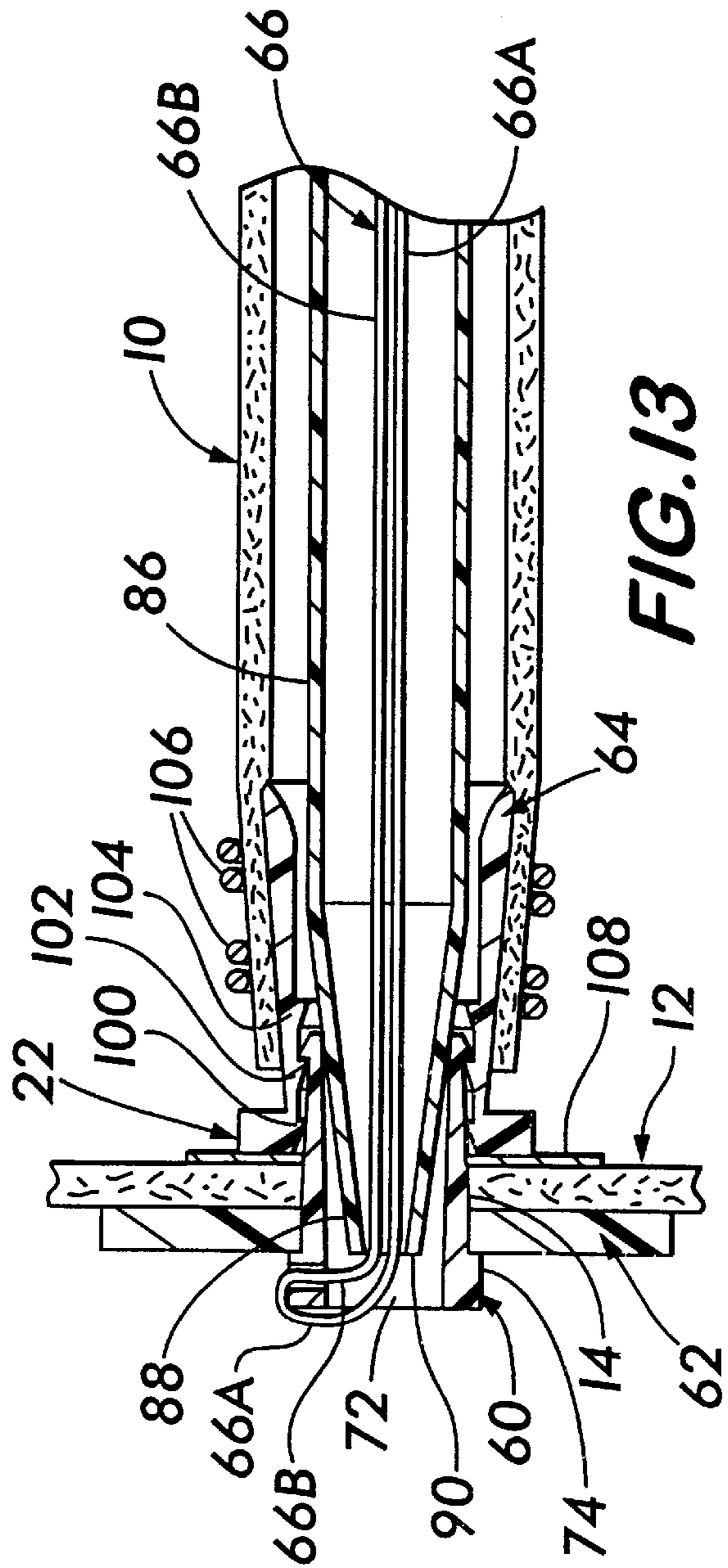
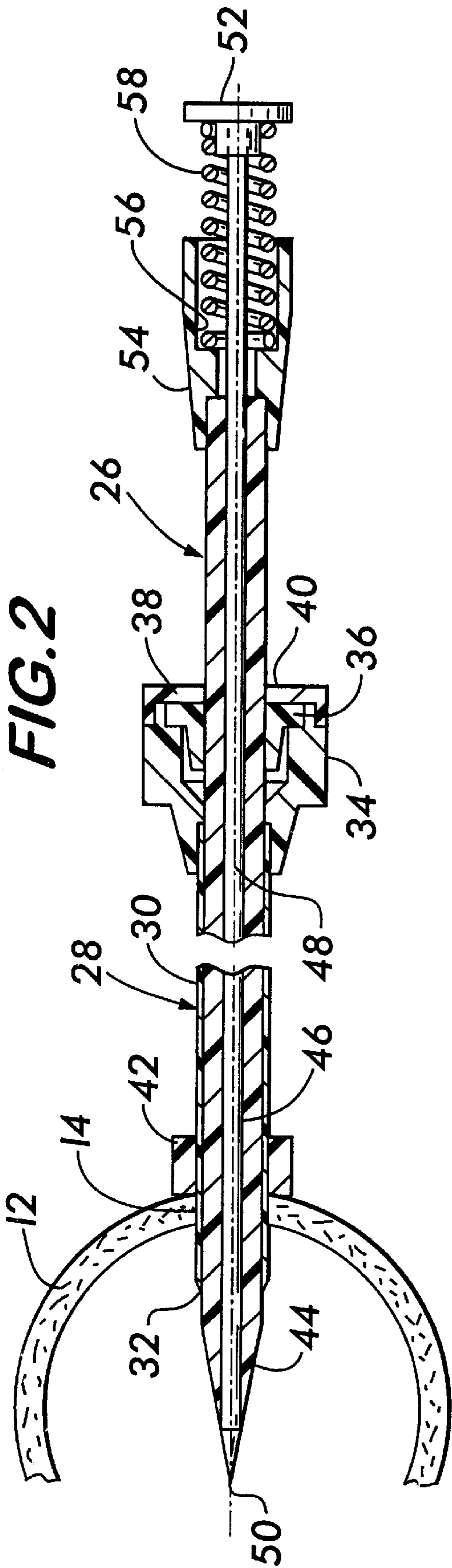


U.S. PATENT DOCUMENTS

5,425,739	6/1995	Jessen .	5,456,714	10/1995	Owen .
5,443,497	8/1995	Venbrux .	5,503,635	4/1996	Sauer et al. .
5,445,644	8/1995	Pietrafitta et al. .	5,509,902	4/1996	Raulerson .
5,447,514	9/1995	Gerry et al. .	5,571,167	11/1996	Maginot .
5,456,712	10/1995	Maginot .	5,586,987	12/1996	Fahy .
			5,591,226	1/1997	Trerotola et al. .

FIG. 1





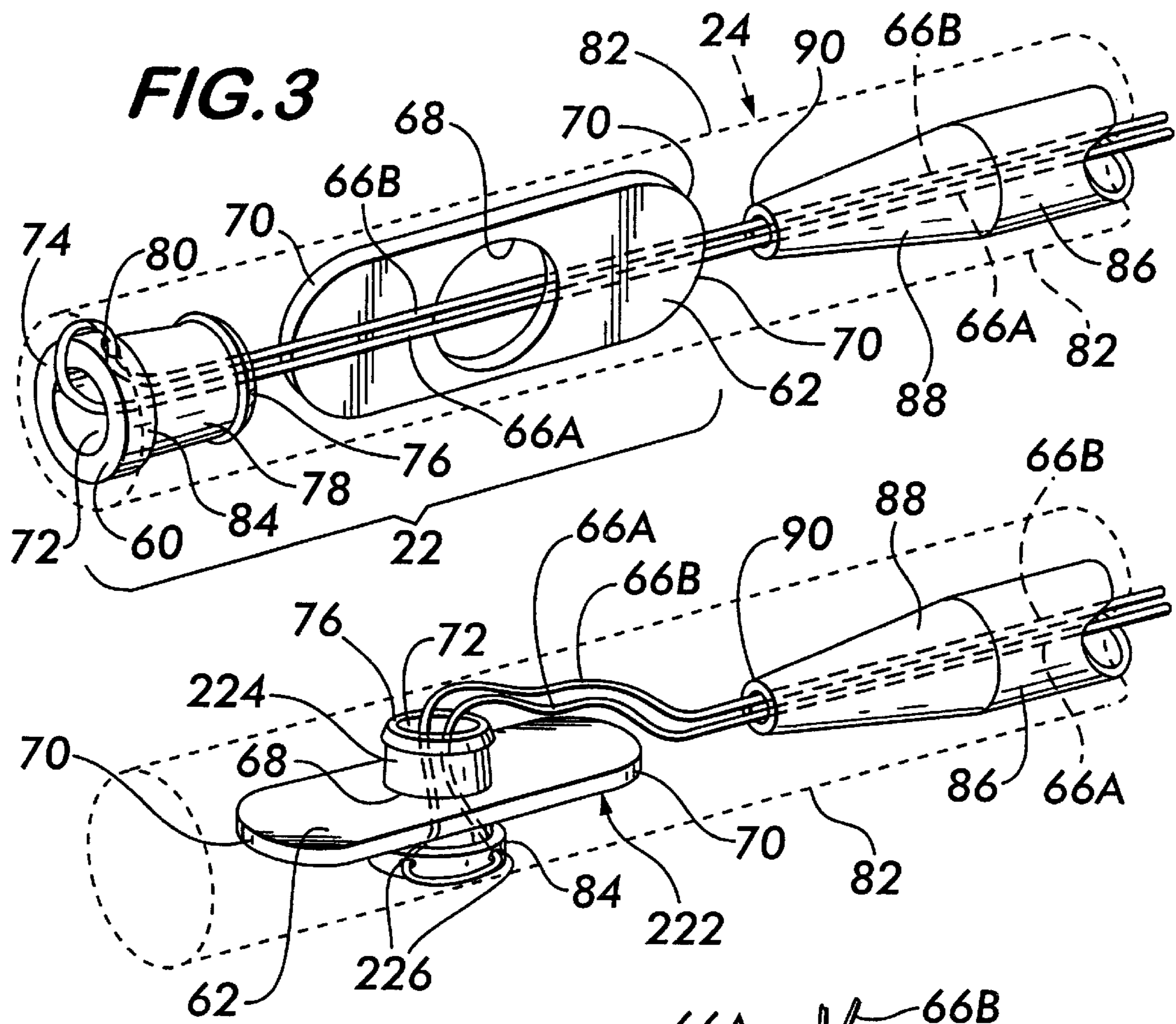


FIG. 4

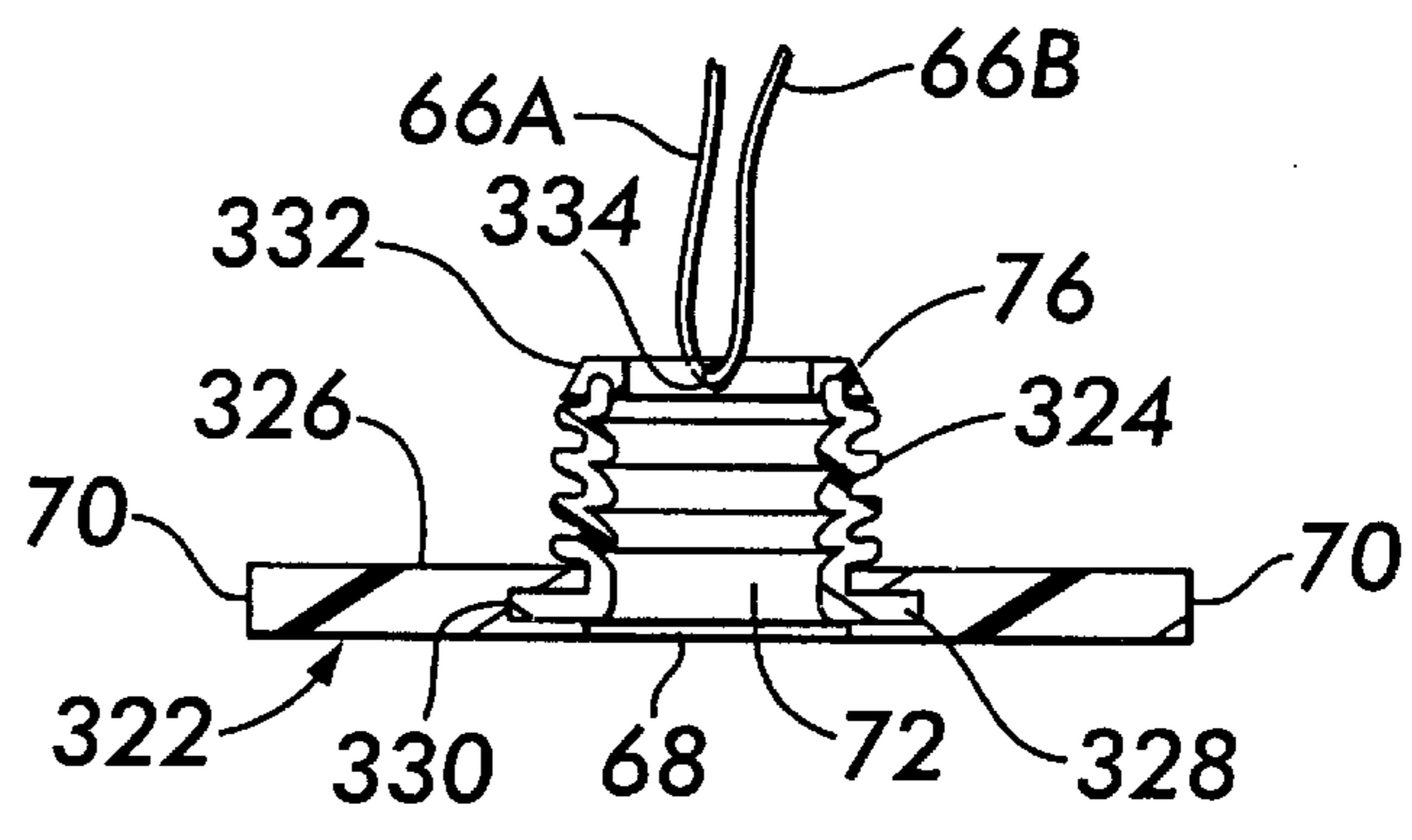


FIG. 5

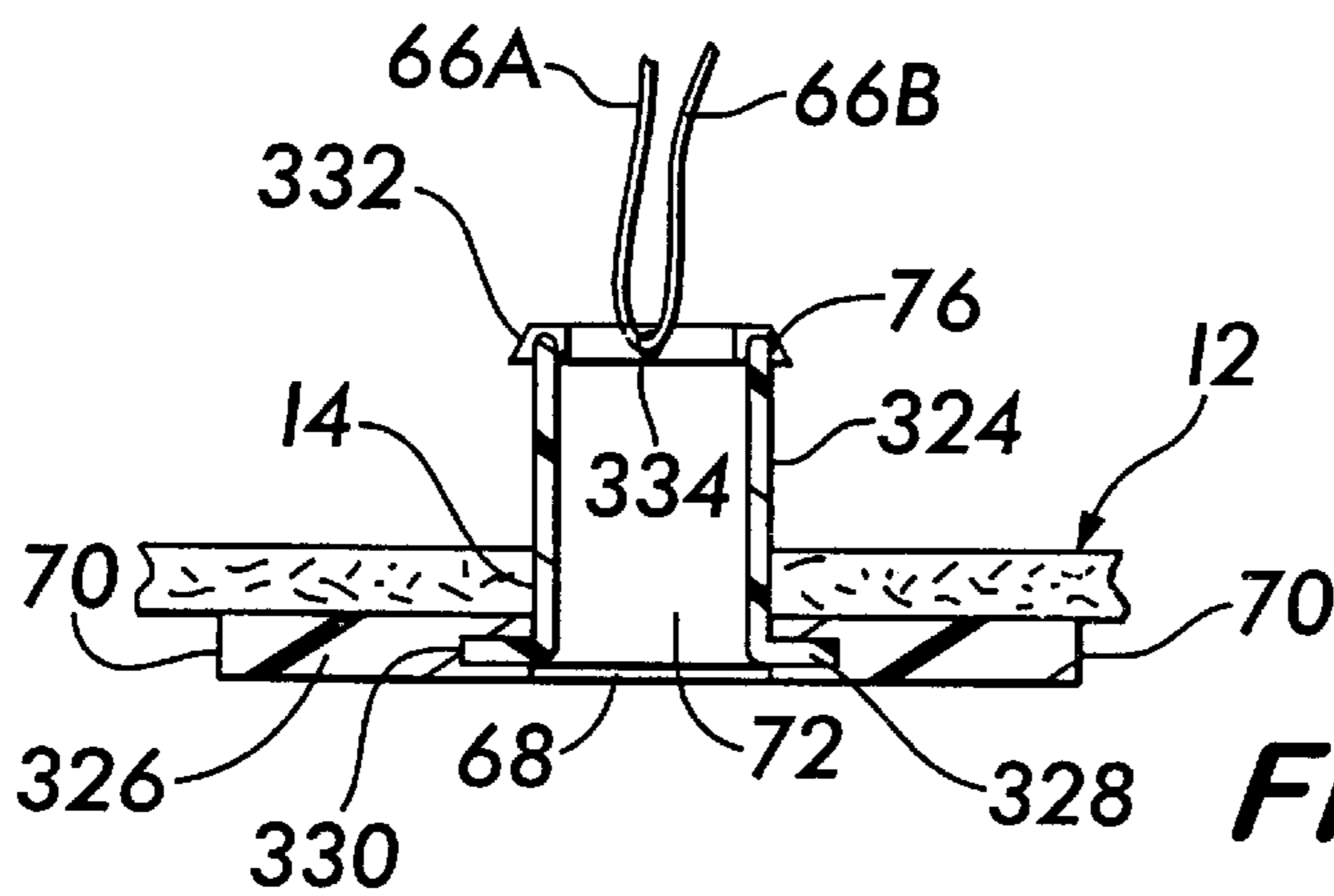


FIG. 6

FIG. 7

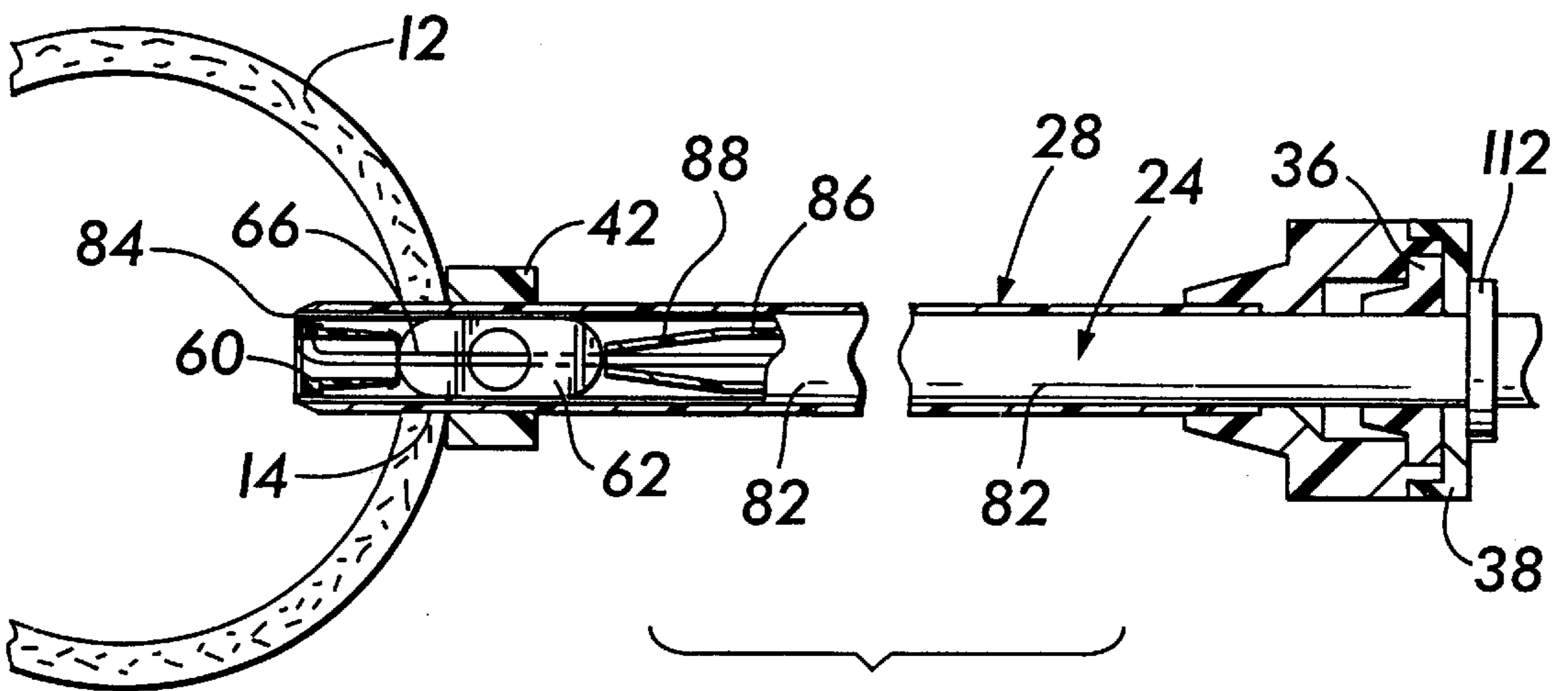
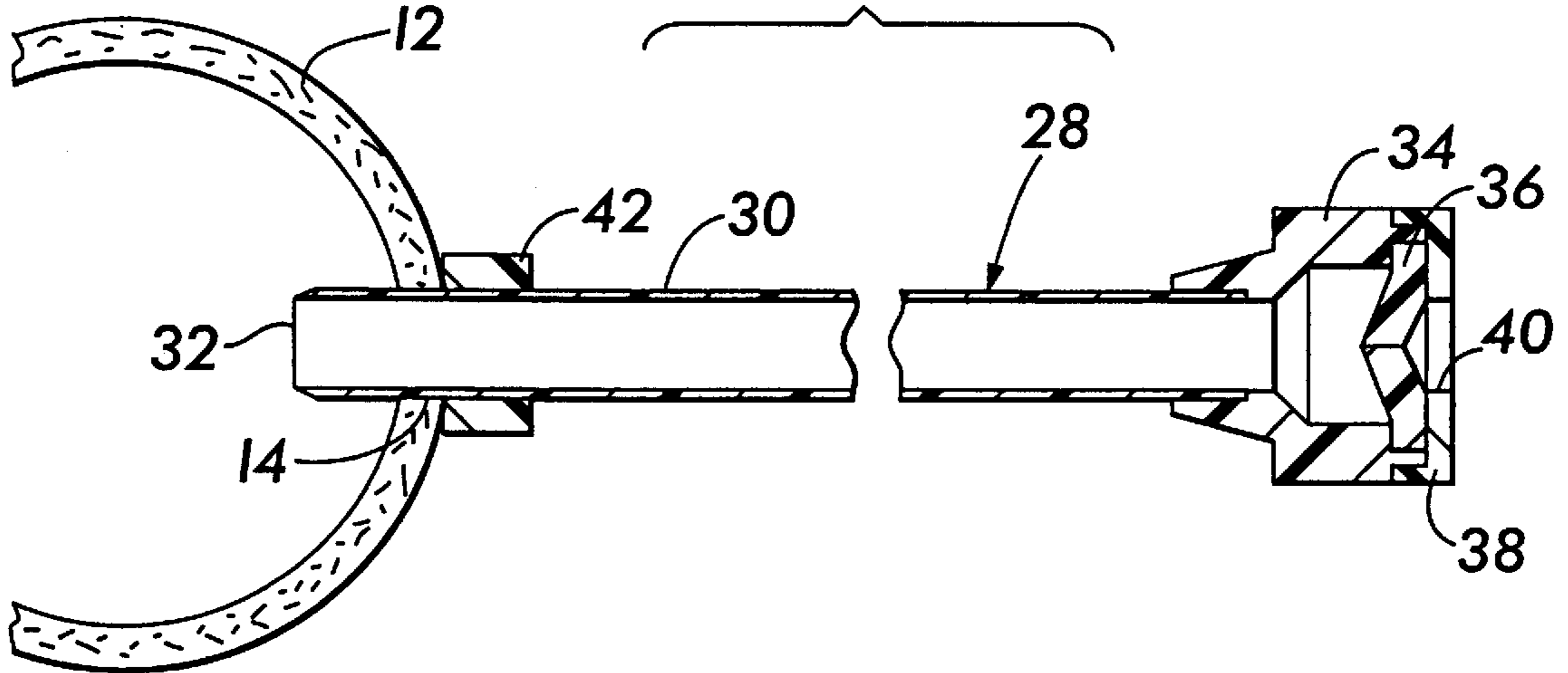
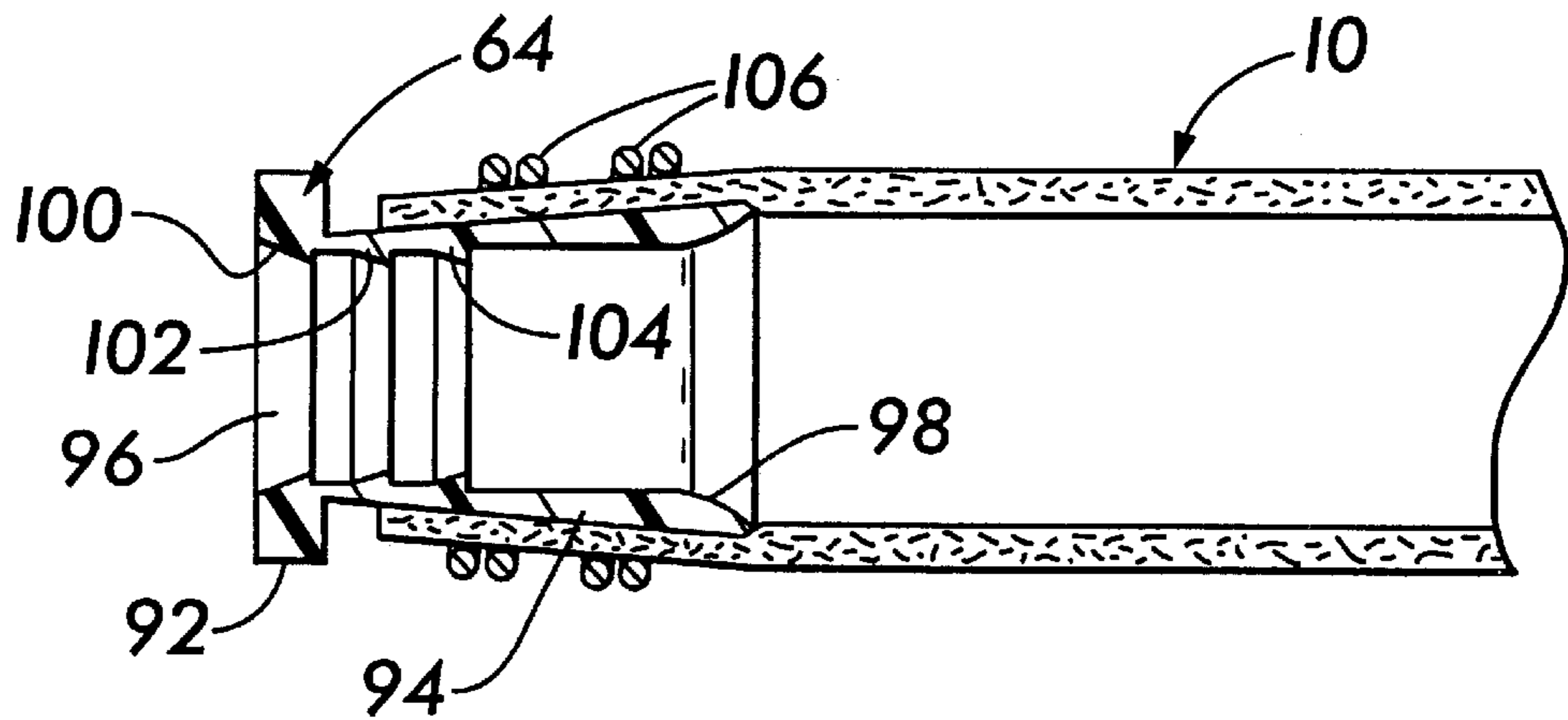
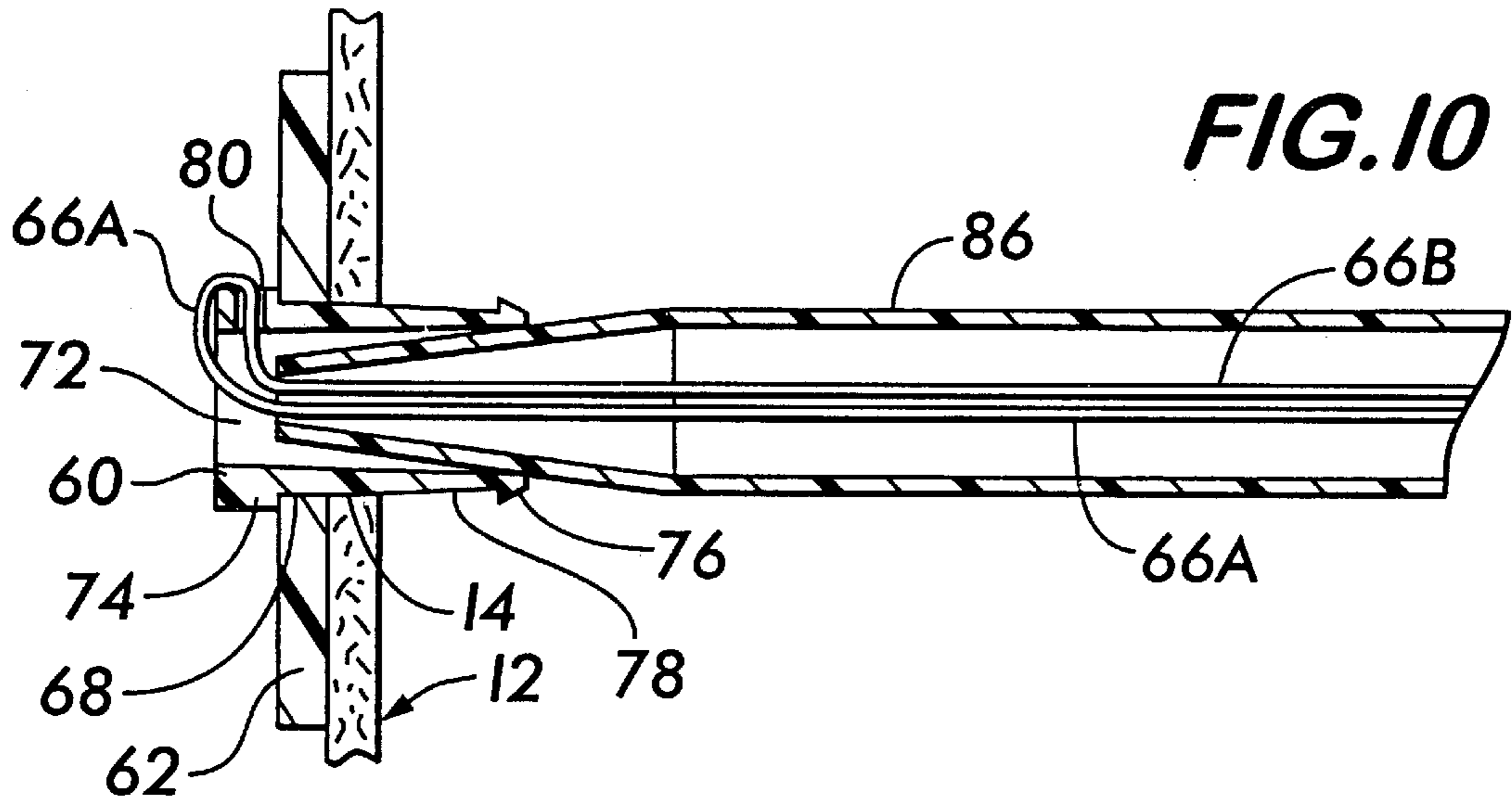
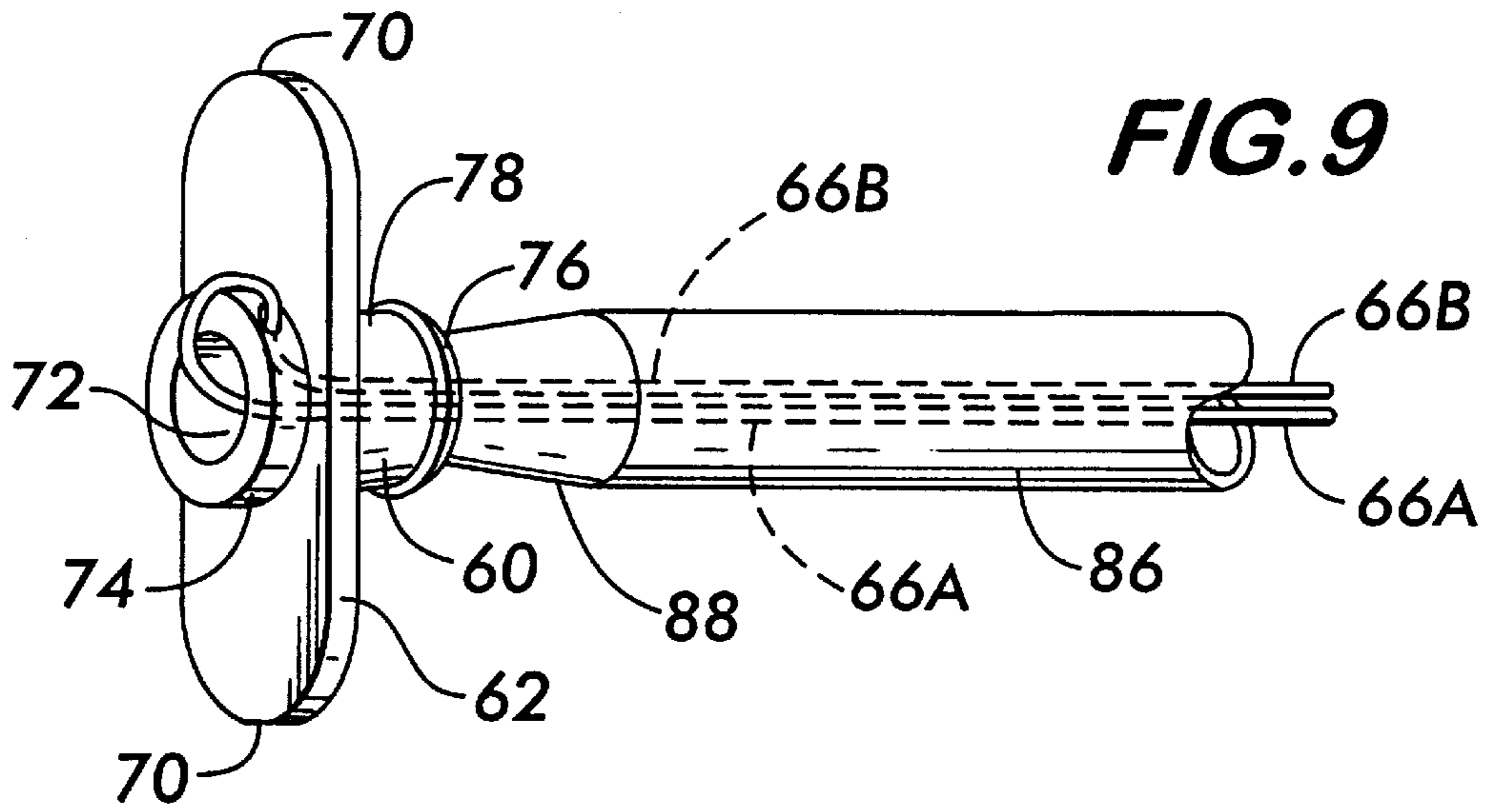


FIG. 8



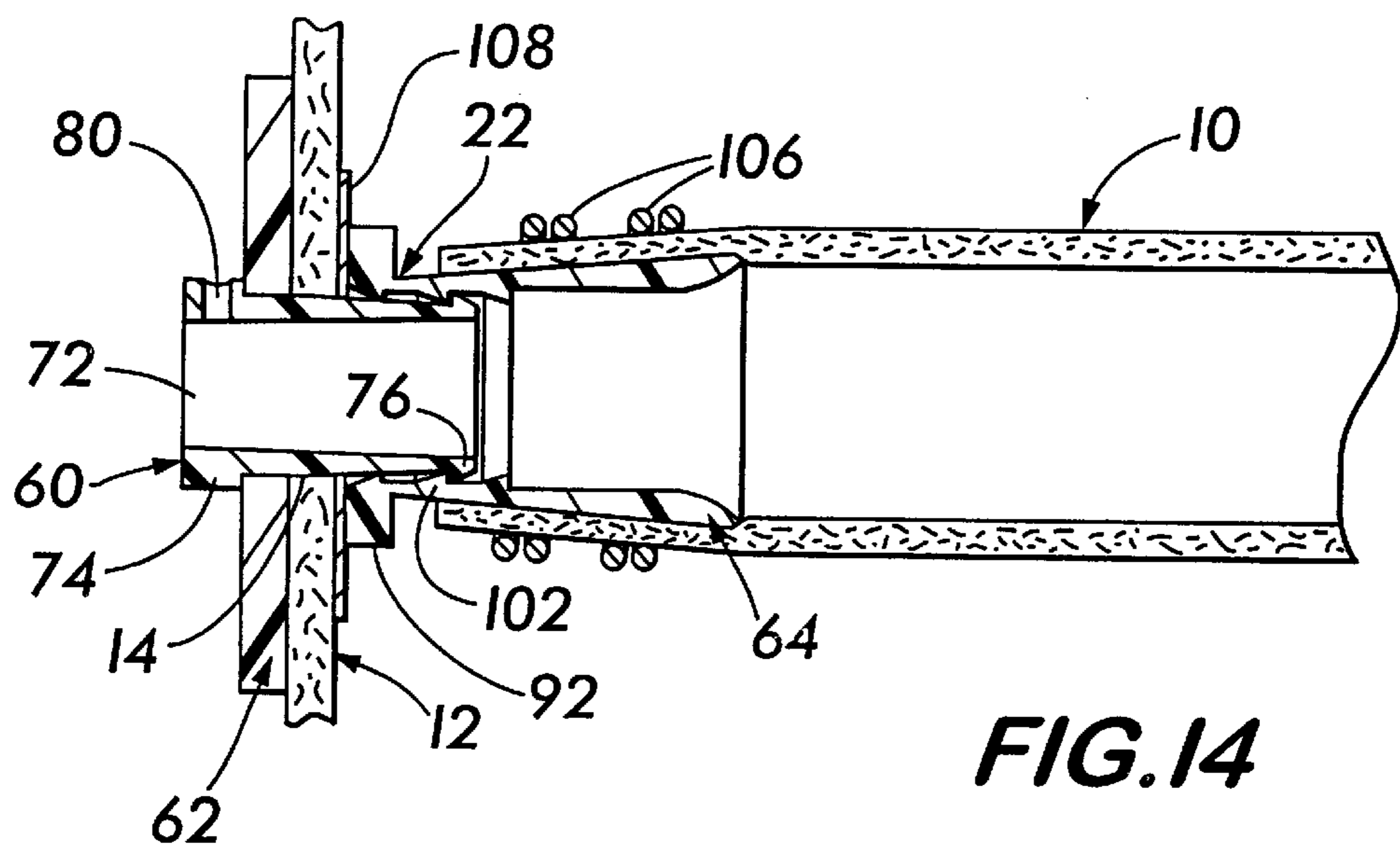
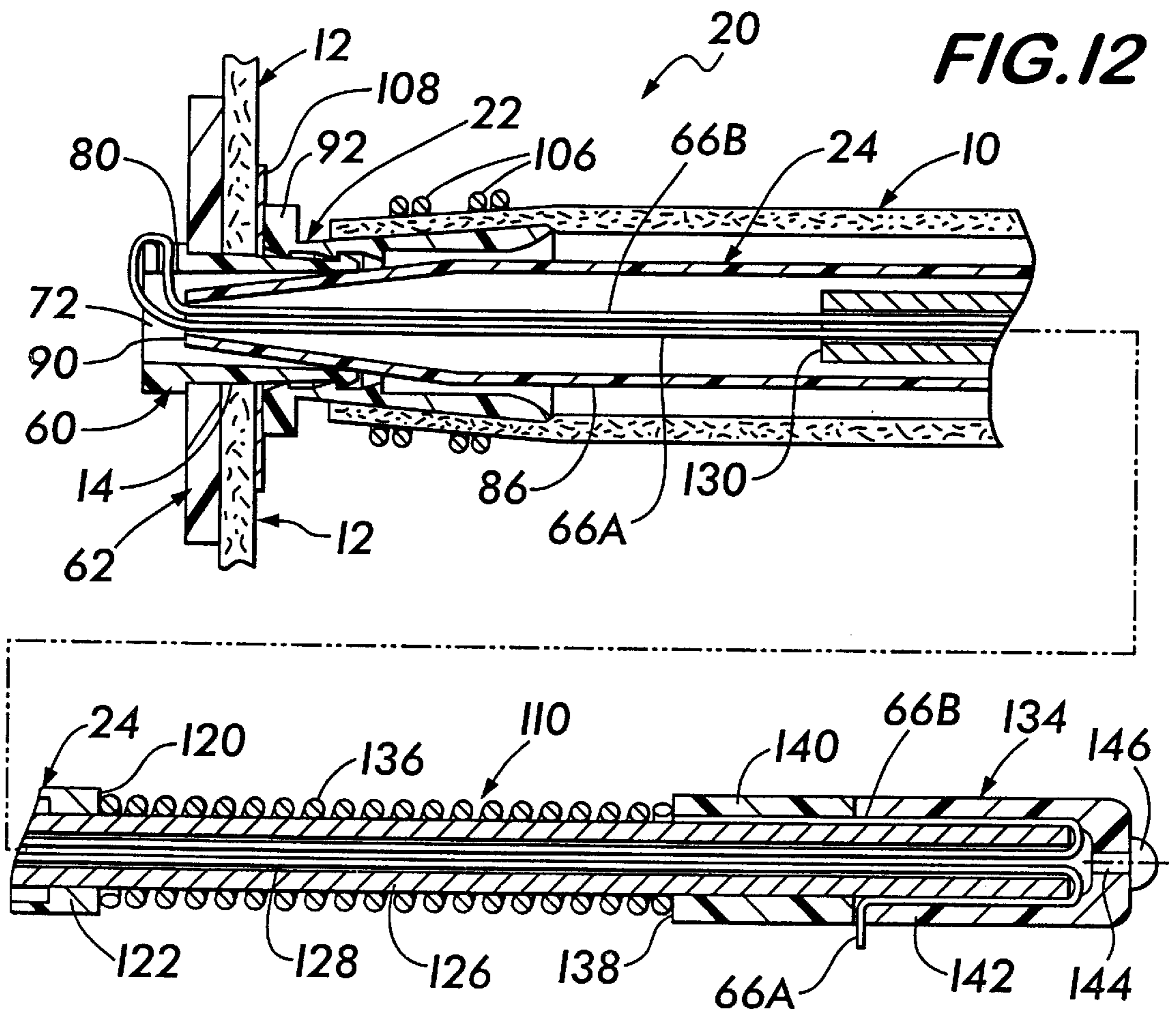
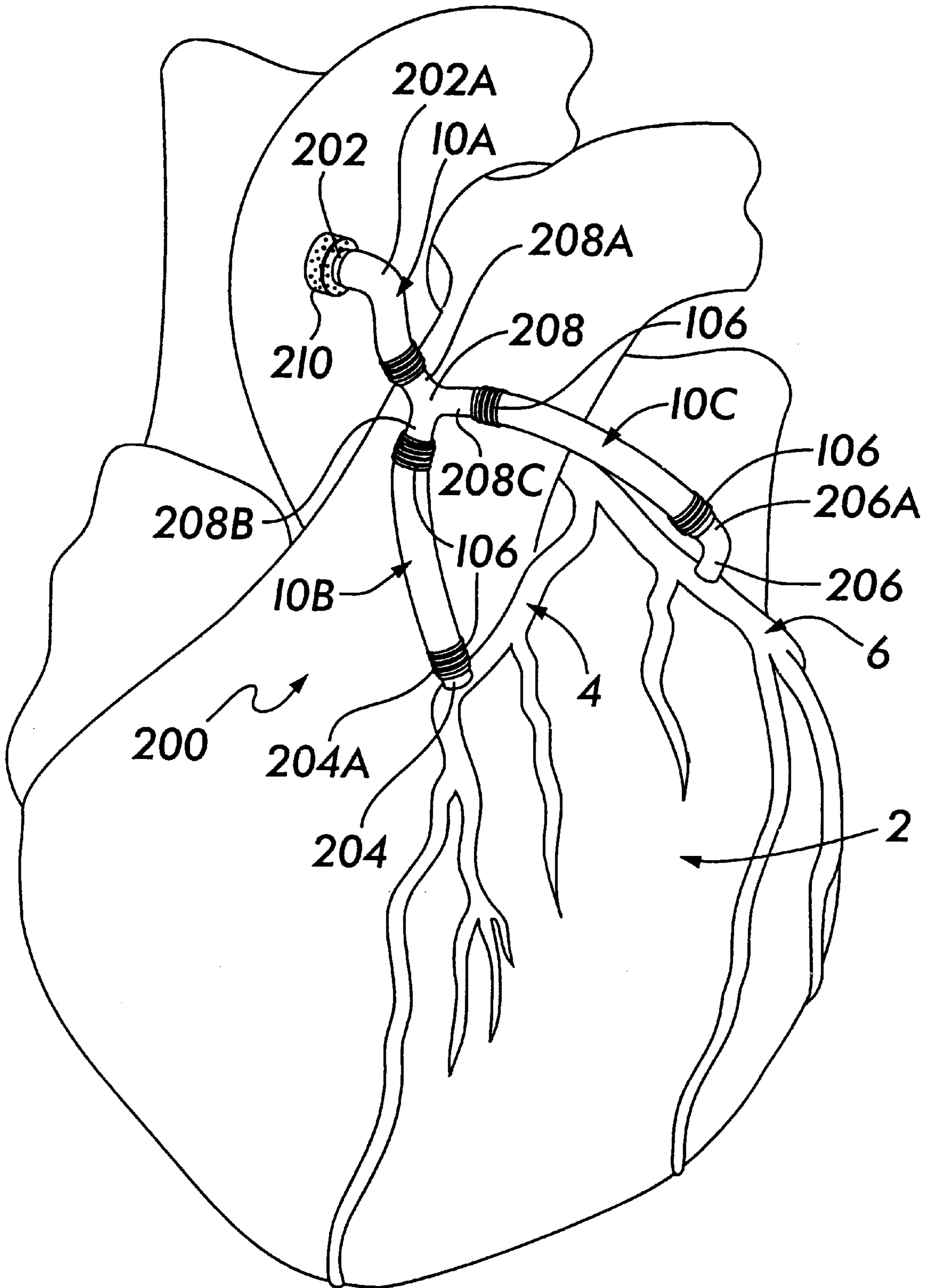


FIG. 15



BIFURCATED CONNECTOR SYSTEM FOR CORONARY BYPASS GRAFTS AND METHODS OF USE

This application is a Continuation-In-Part of our earlier application Ser. No. 08/923,682, filed on Sep. 4, 1997, entitled Connector System For Vessels, Ducts, Lumens Or Hollow Organs And Methods Of Use, which application is assigned to the same assignee as this invention and whose disclosure is incorporated by reference herein (hereinafter the "'682 application").

BACKGROUND OF THE INVENTION

This invention relates generally to medical devices and methods of performing surgical procedures and more particularly to the anastomosis of blood vessels, ducts, lumens or other tubular organs.

Arterial bypass surgery is a common modality for the treatment of occlusive vascular disease. Such surgery typically involves a formal surgical incision and exposure of the occluded vessel followed by the joinder of a graft, e.g., a mammary artery, saphenous vein, or synthetic graft (all collectively referred to hereinafter as the "bypass graft"), to the occluded vessel (hereinafter the "native" blood vessel) distally (downstream) of the occlusion. The upstream or proximal end of the bypass graft is secured to a suitable blood vessel upstream of the occlusion, e.g., the aorta, to divert the flow of blood around the blockage. Other occluded or diseased blood vessels, such as the carotid artery, may be similarly treated. Moreover, similar procedures are conducted to place a graft between an artery and a vein in dialysis patients.

While such surgical procedures are widely practiced they have certain inherent operative limitations. For example, sewing the graft to the host vessel, known as anastomosis, requires complex and delicate surgical techniques to accomplish the optimum result. Various complications must be avoided when anastomosing a bypass graft, whether it be a natural graft or a synthetic graft. For example, it is important that the juncture between the native vessel and the bypass graft form a smooth uniform transition without narrowing or regional irregularities which could tend to reduce blood flow. Moreover, any protuberances into the lumen could obstruct blood flow and may produce turbulence, thereby increasing the risk of clotting and/or restenosis. In addition, the difference in size between the typically larger internal diameter of the bypass graft and the typically smaller native artery may also produce unwanted turbulence in the blood. All of these characteristics can greatly diminish the effectiveness and patency of the graft.

Various devices and methods of use have been disclosed for effecting anastomosis of blood or other vessels, ducts, lumens or other tubular organs. Examples of such devices and methods are found in U.S. Pat. Nos. 2,127,903 (Bowen), 3,155,095 (Brown), 3,588,920 (Wesolowski), 3,620,218 (Schmitt et al.), 3,683,926 (Suzuki), 4,214,586 (Mericle), 4,233,981 (Schomacher), 4,366,819 (Kasler), 4,368,736 (Kasler), 4,470,415 (Wozniak), 4,501,263 (Harbuck), 4,675,008 (Tretbar), 4,512,761 (Raible), 4,552,148 (Hardy, Jr. et al.), 4,721,109 (Healy), 4,753,236 (Healy), 4,769,029 (Patel), 4,851,001 (Taheri), 4,816,028 (Kapadia et al.), 4,854,318 (Solem et al.), 4,930,502 (Chen), 4,931,057 (Cummings et al.), 4,957,499 (Lipatov et al.), 5,156,619 (Ehrenfeld), 5,123,908 (Chen), 5,192,289 (Jessen), 5,250,058 (Miller), 5,222,963 (Brinkerhoff et al.), 5,330,490 (Wilk et al.), 5,346,501 (Regula et al.), 5,364,389 (Anderson),

5,399,352 (Hanson), 5,425,738 (Gustafson et al.), 5,425,739 (Jessen), 5,443,497 (Venbrux), 5,445,644 (Pietrafitta et al.), 5,447,514 (Gerry et al.), 5,456,712 (Maginot), 5,456,714 (Owen), 5,503,635 (Sauer et al.), 5,509,902 (Raulerson), 5,571,167 (Maginot), 5,586,987 (Fahy) and 5,591,226 (Trerotola et al.).

In our copending U.S. patent application Ser. No. 08/861,584 filed on May 22, 1997 entitled Anastomosis System And Method of Use, which is assigned to the same assignee as this invention and whose disclosure is incorporated by reference herein (hereinafter the "'584 application"), there is disclosed and claimed anastomosis systems and methods of use which overcome many of the disadvantages of the prior art.

Notwithstanding the inventions of the '584 and '682 applications, a need is still deemed to exist for effecting the bypass of two or more vessels, ducts, lumens or hollow organs by means of a common anastomosis connector.

OBJECTS OF THE INVENTION

It is a general object of this invention to provide connection, e.g., anastomosis, systems for coronary bypass grafts and methods of use which furthers the state of the art.

It is a further object of this invention to provide a system and method of use for quickly, easily and safely effecting the anastomosis of a bifurcated bypass graft to a native blood vessel e.g., the aorta, and two downstream native blood vessels, e.g., two coronary arteries.

SUMMARY OF THE INVENTION

These and other objects of the instant invention are achieved by providing a system for effecting the bypass of portions of at least two downstream native blood vessels, e.g., the left anterior descending coronary artery and the circumflex coronary artery, from an upstream native blood vessel, e.g., the aorta, within the body of a living being by use of at least two bypass grafts. The downstream native blood vessels and the upstream native blood vessel each have a wall with an opening provided therein.

The system basically comprises a first upstream anastomosis connector for connection to the native upstream blood vessel and at least two downstream anastomosis connectors. The downstream anastomosis connectors are arranged for connecting the at least two bypass grafts to respective ones of the at least two downstream native blood vessels and to the upstream native blood vessel, e.g., the downstream ends of the bypass grafts are connected by associated snap-connector members to the downstream connectors. The upstream connector includes an internal portion arranged to be extended through the opening in the upstream blood vessel for communication with the interior of the upstream blood vessel and an external portion arranged to extend outside the upstream blood vessel. Similarly, each of the downstream anastomosis connectors includes an internal portion arranged to be extended through the opening in a respective downstream native blood vessel for communication with the interior of the respective downstream native blood vessel and an external portion arranged to extend outside the respective downstream native blood vessel, e.g., for snap-connection to the snap connector members at the downstream ends of the bypass grafts.

The anastomosis connectors of the system are arranged to be coupled together to establish a path for carrying blood through the anastomosis connectors from the upstream native blood vessel through the at least two bypass grafts to the respective downstream native blood vessels.

In a preferred embodiment of the invention the system also includes a midstream anastomosis connector having an inlet port and at least two outlet ports. The inlet port of the midstream anastomosis connector is arranged to be coupled, e.g., connected via another bypass graft and associated snap-connector members, to the external portion of the upstream anastomosis connector, while the outlet ports of the midstream anastomosis connector are arranged to be coupled, e.g., connected via associated snap connector members, to the upstream ends of respective ones of the bypass grafts.

DESCRIPTION OF THE DRAWING

Other objects and many of the attendant advantages of this invention will become readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawing wherein:

FIG. 1 is a longitudinal sectional view of one embodiment of a first connector assembly and a deployment instrument which form a portion of the connector system of this invention for creating a fluid access port in a vessel, duct, lumen or tubular organ or for effecting the anastomosis between two vessels, ducts, lumens or tubular organs within the body of a living being;

FIG. 2 is a longitudinal sectional view of a piercing instrument and an introducer sheath also forming a portion of the connector system of this invention shown during the process of forming a small opening in the wall of the vessel, duct, lumen or tubular organ;

FIG. 3 is an enlarged, isometric view of the embodiment of the connector assembly of FIG. 1 shown in its "stowed" state disposed within the deployment instrument of this invention prior to its deployment;

FIG. 4 is an enlarged isometric view, similar to FIG. 3, but showing another embodiment of a connector assembly constructed in accordance with this invention and shown in its "stowed" state prior to its deployment;

FIG. 5 is a longitudinal sectional view showing yet another embodiment of a connector assembly constructed in accordance with this invention shown in its compact or "stowed" state prior to its deployment;

FIG. 6 is a longitudinal sectional view, similar to FIG. 5, but showing the embodiment thereof in its deployed state extending through an opening in the wall of a vessel, duct, lumen or tubular organ;

FIG. 7 is a longitudinal sectional view of the introducer sheath shown in FIG. 2 extending into an opening formed within a vessel, duct, lumen or tubular organ;

FIG. 8 is a longitudinal sectional view, similar to FIG. 7, but showing the deployment instrument extending through the introducer sheath to deploy the connector assembly of FIG. 1 into the interior of the vessel, duct, lumen or tubular organ;

FIG. 9 is an isometric view of the connector assembly of FIG. 1, shown being assembled in its "deployed" state;

FIG. 10 is a longitudinal sectional view of the connector assembly of FIG. 1 shown during the deployment thereof in the opening in the wall of the vessel, duct, lumen or tubular organ;

FIG. 11 is a longitudinal sectional view of another connector component forming another portion of the connector assembly of FIG. 1 and with a second vessel, duct, lumen or tubular organ secured thereto for forming an anastomotic connection between the two vessels, ducts, lumens or tubular organs;

FIG. 12 is a longitudinal sectional view of the deployment instrument of FIG. 1 showing the formation of the anastomosis connection between the two vessels, ducts, lumens or tubular organs;

FIG. 13 is an enlarged longitudinal sectional view of the distal end of the deployment instrument of FIG. 12 during the anastomosis connecting procedure;

FIG. 14 is a longitudinal sectional view showing the completed anastomotic connection between the two vessel, ducts, lumens or tubular organs; and

FIG. 15 is an illustration of a anastomosis connector system of the subject invention used to effect the bypass of occluded portions of two downstream native arteries, e.g., the left anterior descending coronary artery and the circumflex coronary artery, from an upstream artery, downstream anastomosis connectors, and a common midstream bifurcated anastomosis connector.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown at 20 in FIG. 1 a connector system constructed in accordance with the subject invention. The system can be used to effect the anastomosis of any two vessels, ducts, lumens or tubular organs. In fact, the system 20 can be used to form a fluid access port in any vessel, duct, lumen or tubular organ.

One particularly useful anastomosis application of the subject system is for effecting the bypass of an occluded coronary artery. This may be accomplished by forming an anastomotic connection between a saphenous vein graft and the aorta upstream of the occluded coronary artery. The completed anastomotic connection between the bypass graft and the aorta is shown in FIG. 14, wherein the bypass graft is designated by the reference numeral 10 and the aorta by the reference numeral 12.

The system basically comprises a first connector assembly 22 (FIGS. 1 and 14), a deployment instrument 24 (FIGS. 1 and 12), a piercer-dilator instrument 26 (FIG. 2) and an introducer sheath 28 (FIGS. 2 and 7). The deployment instrument 24 will be described in considerable detail later. Suffice it for now to state that the instrument 24 is arranged to house a portion of the connector assembly 22 therein and to deploy it within an opening formed in the wall of the vessel, duct, lumen or tubular organ so that a fluid access port or an anastomosis connection can be completed. As will also be described later, the deployment instrument 24 is arranged to be used after the piercer-dilator instrument (or some other means not shown) has formed a small opening 14 (FIG. 2) in the wall of the vessel, duct, lumen or tubular organ 12 to which the fluid access port or anastomosis connection is to be made and the introducer sheath 28 has been located within that opening.

Before describing the details of the piercer-dilator instrument 26, a brief description of the introducer sheath 28 is in order. To that end, as can be seen best in FIG. 7, the introducer sheath is of generally conventional construction and includes an elongated tubular body 30, e.g., an 8-14 French tube. The tubular body is formed of a biocompatible material, such as plastic, and has an open distal end 32 and closed proximal end 34. The proximal end 34 is closed by means of a conventional hemostasis valve housing including a resilient valve member 36 disposed therein. A sealing cap 38 holds the valve member 36 in place and includes a central opening 40 through which any suitable elongated member or

instrument can be passed through the valve member **36** and the associated tube **30**. As will be described hereinafter the piercer-dilator **26** is extended through the introducer sheath **28** and those two devices are used together to form the small opening **14** in the vessel, duct, lumen or tubular organ. Once the opening **14** has been formed, the piercer-dilator is removed from the sheath **28** and the introducer instrument **24** with the connection assembly **22** therein is passed through the introducer sheath to deploy the connector assembly. In order to prevent excessive penetration of the piercer-dilator into the vessel, duct, lumen or tubular organ during the formation of the opening **14** in the wall thereof, the introducer sheath **28** includes an annular stop **42** closely adjacent its open distal end **32**.

Turning now to FIG. **2**, the details of piercer-dilator **26** will now be described. Thus, as can be seen therein, the piercer-dilator **26** basically comprises an elongated tubular body having a tapered distal end **44**. A central passageway **46** extends down the entire length of the body **44**. A needle-plunger **48** extends through the passageway and terminates at its distal end in a sharply pointed tip **50**. The proximal end of the needle-plunger is in the form of an enlarged head or cap **52**. A cup shaped member **54** is mounted on the proximal end of the tubular body **44** of the piercer-dilator **26**. The cup shaped member **54** includes central bore recess **56** arranged to receive one end of a helical compression spring **58**. The other end of the helical spring engages the under surface of the cap **52**. The spring is normally in its uncompressed state. It is shown in FIG. **2** in its compressed state, i.e., the state wherein the plunger cap **52** is pressed in the distal direction with respect to the cup shaped member **54**. This action causes the piercing point **50** of the plunger to extend out of the opening at the tapered distal end of the dilator body **44**. It is in this condition that the piercer-dilator is used to form the small opening **14** in the wall of the vessel, duct, lumen or tubular organ to which the access port or anastomosis connection is to be made. To that end, the piercer-dilator **26** is introduced through the hemostasis valve in the introducer sheath **28** until its distal end extends slightly beyond the open free end **32** of the sheath **28**. A stop (not shown) is provided to ensure that the tip of the needle-dilator body does not extend too far beyond the open end of the sheath. With the needle-dilator in place the plunger cap **52** is pressed, i.e., moved distally with respect to the body of the piercer-dilator, whereupon the piercing point **50** extends out of the piercer-dilator. The exposed pointed tip **50** of the piercer-dilator instrument is then brought into engagement with the outer surface of the vessel, duct, lumen or tubular body, e.g., the aorta **12**, at which the opening **14** is to be formed. The introducer sheath and the piercer-dilator are then pushed distally in through the wall of the vessel, duct, lumen or tubular organ, whereupon a small opening is formed. Further pushing of the needle-dilator into the opening enlarges it as the flared conical surface of the distal free end of the dilator body **44**. Further pushing in the distal direction on the piercer-dilator instrument **26** and the introducer sheath **28** as a unit causes the distal end of the introducer sheath to enter into the opening **14**. The combined piercer-dilator instrument and the introducer sheath are pushed inward until the stop **42** engages the outer surface of the wall of the vessel, duct, lumen or tubular organ. At this point, no further penetration can be made. Thus, the stop prevents the piercing tip from engaging the wall of the vessel, duct or lumen opposite the opening **14**. Once the opening has been formed, the piercer-dilator **26** can then be removed by retracting or pulling on it proximally to withdraw it out of the introducer sheath **28** while leaving the

introducer sheath in place, such as shown in FIG. **7**. The system **20** is now ready for the use of the deployment instrument **24** to deploy the connector assembly **22** through the opening **14** into the interior of the vessel, duct, lumen or tubular organ.

Before describing the details of the deployment instrument **24**, a description of the connector assembly **22** is in order given. To that end, as can be seen clearly in FIGS. **1**, **3**, **9** and **11**, the connector assembly **22** basically comprises a first connector member **60**, an anchor member **62** and a second connector member. The first connector member and the anchor member are arranged to be deployed within the interior of the vessel, duct or lumen and then to be moved with respect to each other to assemble them in a manner whereupon the anchor member engages the interior of the vessel, duct, lumen or tubular organ contiguous with the opening **14** and a portion of the first connector member extends out through the opening **14** to provide a fluid access port or a connection point for the second connector member **64**. In some applications, the first connector member and the anchor member can be used in and of themselves to form a fluid access port to the interior of the vessel, duct, lumen or tubular organ.

As can be seen clearly in FIG. **3**, the first connector member **60** and the anchor member **62** are coupled together by a positioning member, e.g., a flexible filament **66**. The filament is preferably in the form of a conventional resorbable monofilament suture (or if desired a non-resorbable suture).

The anchor member **62** is an elongated strip formed of a resorbable, somewhat rigid material, such as polyglactide, polyglycolide or copolymers thereof. Non-absorbable materials, e.g., stainless steel, can be used for the anchor member. Each end of the anchor member **62** is rounded at **70**. The first connector member **60** basically comprises a tubular body, preferably formed of the same material as that forming the anchor **62**, and having a central passageway **72** extending therethrough. One end of the tube **74** is in the form of an annular flange. The flange need not be annular, and thus may merely be a tab or projection. The other end of the tube is in the form of at least one undercut annular lip or detent **76** whose exterior surface is chamfered. The outer surface **78** of the tubular connector body **60** between the flange **74** and the detent **76** is somewhat conical, i.e., is in the form of a surface which tapers from the flange **74** to the detent **76**. The maximum outer diameter of the detent **76** of the connector member **60** is just slightly larger than the inside diameter of the hole **68** in the anchor member **62**. A small aperture **80** extends radially outward from the central passageway **72** of the first connector member **60** through the annular flange **74**.

As best seen in FIGS. **1** and **3**, the filament **66** includes a pair of sequentially located sections **66A** and **66B**. In particular, section **66A** extends from the proximal end of the deployment instrument **24** down the interior of that instrument through the central opening **68** in the anchor member **60**, through the central passage **72** in the first connector member **60** from whence it doubles back to merge with the filament section **66B**. The section **66B** extends through the aperture **80** back into the interior passageway **72** in the first connector member **60** and through the central opening **68** in the anchor member **62**. From there the section **66B** of the filament **66** extends in the proximal direction through the deployment instrument to the proximal end thereof.

As mentioned earlier, the details of the deployment instrument will be described later, suffice it for now to state that

this instrument includes a carrier **82** in the form of a tubular body in which the anchor member **62** and the first connector member **60** of the connector assembly **22** are disposed. The carrier tube includes an open, free (distal) end **84**. As can be seen in FIGS. **1** and **3**, the first connector member **60** is disposed within the carrier tube **82** immediately adjacent the open distal end **84**, while the anchor member **62** is disposed immediately proximally of the first connector member.

The deployment instrument **24** also includes a guide-pusher assembly located within the carrier tube. The guide pusher assembly includes a tubular guide-pusher member **86** having a conical distal portion end **88**. The free end **90** of the guide-pusher member includes a small opening communicating with the hollow interior of the guide-pusher and through which the filament sections **66A** and **66B** extend. The end **90** of the pusher member **86** is located immediately adjacent the proximally located rounded distal end **70** of the anchor member **62**, when the anchor member is within the carrier tube in place as shown in FIGS. **1** and **3**.

Deployment of the first connector member **60** and anchor member **62** is accomplished by operating the guide-pusher assembly, as will be described later, to cause the guide-pusher member **86** to push on the proximal end portion **70** of the anchor member **62** which in turn pushes on the distally located connector member **60** to expel the first connector member **60** out of the open free end **84** of the carrier member and out of the open end **32** of the introducer sheath **28** into the interior of the vessel, duct, lumen or tubular organ. Continued pushing on the guide pusher **86** in the distal direction then ejects the anchor member **62** into the interior of the vessel, duct, lumen or tubular organ.

In order to assemble the first connector member and anchor member and cause the detent end of the first connector member to be extended through the opening **14** in the wall of the vessel, duct, lumen or tubular organ, the two extending sections **66A** and **66B** of the filament **66** are retracted in the proximal direction, by means forming a portion of the instrument **24** to be described later. In particular, this retraction action on the filament sections pulls the first connector member toward the anchor member, whereupon the chamfered surface **76** of the first connector member enters into the central opening **68** in the anchor member. Continued retraction on the filament causes the anchor member to engage the interior surface of the vessel, duct, lumen or tubular organ contiguous with the opening **14** with the central opening **68** in the anchor member overlying the opening **14**. Continued retraction of the two filament sections pulls the first connector member further into the central opening **68** in the anchor member, whereupon the portions of the anchor member contiguous with the central opening ride up the surface **78** of the first connector member until the flange **74** of the first connector member abuts the distally directed top surface of the anchor member **62**, as shown in FIGS. **9** and **10**. The retraction of the first connector member through the central opening **68** in the anchor member **62** causes the chamfered proximal end of the first connector member to pass through the opening **14** in the wall of the vessel, duct, lumen or tubular organ **12**, as shown in FIG. **10**. During the retraction of the filament sections **66A** and **66B**, the guide-pusher member **86** remains stationary so that its tapered distal end **88** enters into the central passageway **72** of the first connector member **60** when the first connector member is pulled through the opening **14** in the wall of the vessel, duct, lumen or tubular organ. Thus, the tapered end of the guide-pusher member **86** serves to guide or orient the first connector member **60** so that its central longitudinal axis is disposed generally perpendicularly to the wall of the vessel, duct, lumen or tubular organ **12**, as shown in FIG. **10**.

With the first connector member **60** and the anchor member **62** deployed as shown in FIG. **10**, the system is now ready to complete the anastomosis. To that end, the second connector member **64** is pre-mounted on the distal end of any desired vessel, duct, lumen or tubular organ like that shown in FIG. **11**. For example, as shown in FIG. **11**, the connector **64** can be disposed and secured within the open distal end of a saphenous vein bypass graft **10**. The second connector member basically comprises a hollow tubular member, formed of the same material as that of the first connector **60** and the anchor member **62**. The distal end of the second connector **64** is in the form of an annular flange **92**. The outer surface of the tubular connector **64** proximally of the flange **92** is in the form of a slightly outwardly tapering conical surface **94**, i.e., a surface whose diameter increases linearly in the proximal direction. A central passageway **96** extends through the length of the connector member **64**, the proximal end of the passageway **96** forms a flared throat **98**. Three annular undercut detent rings **100**, **102** and **104** extend about the inter-periphery of the central passageway **96** at closely spaced locations adjacent the flanged distal end **92** of the connector **64**. The outer surface of each of these detents is chamfered and is arranged to cooperate and engage the chamfered surface of the detent **76** of the first connector member **60** to lock the two connector members together, as will be described later. The flared proximal end of the second connector **64** is located within the hollow interior lumen of the bypass graft **10** and is secured in place therein by plural stainless steel springs **106**. The springs extend about the periphery of the distal end of the bypass graft to interpose that portion of the bypass graft tightly between the springs and the exterior surface **94** of the second connector member **64**. Thus, the second connector member is fixedly secured to the distal end of the bypass graft.

The bypass graft with the second connector member fixedly secured thereto as shown in FIG. **11** is arranged to be deployed or slid down over the deployment instrument **24**, as will be described later, and over the guide-pusher member **86** like shown in FIG. **13**, whereupon the flange **92** of the second connector member **64** abuts the exterior surface of the vessel, duct, lumen or tubular organ contiguous with the opening **14** therein. The undercut surface of the detent surface **76** of the first connector member engages one of the undercut surfaces of the three chamfered detent rings **100**, **102** or **104**, with the particular detent being engaged being dependent upon the thickness of the wall of the vessel, duct, lumen or tubular organ.

In the embodiment shown in FIG. **13**, the undercut portion of the detent **76** of the first connector member **60** engages the undercut portion of the detent ring **102** of the second connector member **64**. This action effectively sandwiches the wall of the vessel, duct, lumen or tubular organ between the flange **92** of the second connector member **64** and the anchor member **62**, thereby fixedly securing the connector assembly **22** in place within the opening **14**, thereby completing the anastomosis.

In accordance with a preferred embodiment of this invention, a washer **108** is interposed between the flange **92** of the second connector member **64** and the outer surface of the wall of the vessel, duct, lumen or tubular organ contiguous with the opening **14** to prevent bleeding at the interface of the connector assembly and the opening **14** in the wall of the vessel, duct, lumen or tubular organ. The washer is preferably formed of a hemostatic material, e.g., collagen.

As should be appreciated from the previous discussion, the embodiment of the connector assembly **22** described

heretofore makes use of components which are coupled together, but not assembled. By that it is meant that the components are disposed with respect to each other so that they are held in a compact configuration within the carrier tube for expulsion into the interior of the vessel, duct, lumen or tubular organ. Once expelled they are movable or positionable with respect to each other and with respect to the wall of the vessel, duct, lumen or tubular organ to assemble them in their "deployed state." In the deployed state the portions are oriented with respect to each other so that they are resistant to accidental dislodgement within the opening in the wall of the vessel, duct, lumen or tubular organ. In particular, the anchor member, lying against the interior wall of the vessel, duct, lumen or tubular organ contiguous with the opening prevents the deployed connector assembly from falling out of that opening.

In FIG. 4 there is shown an alternative embodiment of a connector assembly 222 constructed in accordance with this invention. The assembly 222 is similar in many respects to the connector assembly 22, but in other ways differs. In this connection, the connector assembly 222 includes components which are preassembled so that they are connected to each other prior to deployment. These preassembled components are held in a compact or "stowed" state within the carrier tube 82 so that they can be ejected from the carrier tube as a unit into the interior of the vessel, duct, lumen or tubular organ. Once ejected, the connector assembly 222 can then be retracted in a similar manner to that described heretofore to bring a portion of it into engagement with the wall of the vessel, duct, lumen or tubular organ contiguous with the opening 14 while another portion extends out to that opening for connection to the second connector member 64. The connector assembly 222 basically comprises a first connector member 224, an anchor member 62 and a second connector member 64. The anchor member 62 and the second connector member are identical to those components making up the connector assembly 22. Thus, in the interest of brevity, the details of the anchor component 62 and the second connector component 64 will not be reiterated and the various portions of these components will be given the same reference numerals as given previously.

The first connector member 224 is preferably formed of the same material as that of the anchor member 62. Moreover, the first connector member 224 includes various portions which are constructed similar to the connector member 60 of connector assembly 22. Thus, in the interest of brevity, the portions of the first connector assembly 224 which are similar to those portions of the first connector 60 will be given the same reference numerals. In particular, the first connector member 224 is a tubular member having a central passageway 72 extending through it. The distal end of the connector member 224 is in the form of an annular flange 84 while the proximal end is in the form of a chamfered surface detent 76. The outer surface of the connector between the flange 84 and the detent 76 is of circular profile and extends through the central opening 68 in the anchor member 62 so that the connector member 224 is slidable longitudinally within that opening. The connector assembly 222 is arranged to be disposed in a compact or "stowed" position within the carrier tube 82 of the deployment instrument. In particular, the connector 224 is centered within the opening 68 in the anchor 62, as shown in FIG. 4 to ensure that it has the smallest cross sectional profile for disposition within the carrier tube.

A pair of apertures 226 extend radially inward through the flange 84 to enable the filament 66 to be coupled to the connector member 224. In particular, the filament section

66B extends through the open proximal end of the central passage 72 of the connector member 224 and out through one of the apertures 226. The filament section 66B extends into the other aperture 226. From that point, the filament section 66B extends through the passageway 72 and out the proximal end thereof. The proximal end portions of filament sections 66A and 66B extend through the guide-pusher and through the deployment instrument, as will be described later.

Deployment of the connector assembly 222 is accomplished in a similar manner to that of connector assembly 22. In this regard, the guide-pusher assembly is used to push the assembled connector 224 and anchor 62 out of the carrier tube so that the preassembled connector member 24 and the anchor member 62 are located within the interior of the vessel, duct, lumen or tubular organ. Retraction of the filament sections 66A and 66B brings the proximal end of the connector member 224 back through the opening 14 in the wall of the vessel, duct, lumen or tubular organ. Moreover, retraction of the filament sections causes the top or proximal surface of the anchor member 62 to move into engagement with the inner surface of the vessel, duct, lumen or tubular organ contiguous with the opening 14, thereby causing the anchor member to "hang-up" on that surface. Further, retraction of the filament sections moves the connector member 224 with respect to the anchor member, i.e., it causes the connector member to slide through the hole 68 in the anchor member, so that more of the connector member 224 extends out of the opening in the wall of the vessel, duct, lumen or tubular organ until its flange 84 engages the bottom or distal surface of the anchor member contiguous with the hole 68. At this time, the connector device 224 is fully deployed and ready for connection to the connector member 64 and the bypass graft 10 connected to that connector. That connection is accomplished in the same manner as with the connector assembly 22 described earlier.

In FIG. 5, there is shown another alternative embodiment 32 of a connector assembly constructed in accordance with this invention. The connector assembly 322 is somewhat similar to the connector assembly 222 in that it is preassembled, i.e., its first connector and anchor components are assembled or connected to each other, but are movable relative to each other during the deployment procedure. In the interest of brevity, the common components of the connector assembly 322 and connector assembly 222 and connector assembly 22 will be given the same reference numerals and the details of their construction and operation will not be reiterated. Thus, as can be seen in FIG. 5, the connector assembly 322 basically comprises a first connector member 324 and an anchor member 326. The first connector member 324 and the anchor member 326 are an integral unit, with the anchor unit 326 being similar in construction to the anchor member 62. Thus, the anchor member includes a central hole 68. The first connector member 324 is a collapsible, e.g., a corrugated, tube having a central passageway 72 extending therethrough. The distal end of the corrugated tube 324 is in the form of a flange 328 which is received within a correspondingly shaped annular recess 330 extending about the hole 68 in the anchor member 326. The tube 324 is arranged to be held in its compact or "stowed" state as shown in FIG. 5 when it is within the carrier tube of the deployment instrument, and to be extended to its deployed state, as shown in FIG. 6, during its deployment.

The proximal end of the collapsible corrugated tube 324 is in the form of an annular collar 332 forming a detent having a chamfered surface 76. The collar 332 is fixedly secured to the proximal end of the corrugated tube 324.

The anchor member **326** is preferably formed of a resorbable material, like that of the anchor members described heretofore. The corrugated tube may also be formed of the same resorbable material. Alternatively, it may be formed of any conventional biocompatible material, such as Dacron mesh, providing that it is impervious to the flow of liquid through it so that fluid flowing through the central passageway **72** will not leak out the wall of the corrugated tube **324** much like a synthetic vascular graft.

A radially oriented aperture **334** is provided in the annular collar **332** through which the filament **66** extends so that one filament section **66B** extends from one side of the aperture while the other filament section **66A** extends from the other.

The connector assembly **322** is disposed within the carrier tube **82** in its compact state like that shown in FIG. **5**, so that its anchor member is oriented parallel to the central longitudinal axis of the carrier tube and immediately distally of the distal end **90** of the guide-pusher member **86**. The filament sections **66A** and **66B** extend back through the interior of the guide-pusher and through the deployment instrument. The connector assembly **322** is ejected from the carrier tube in the same manner as described with reference to the connector assemblies **22** and **222**. Once ejected into the interior of the vessel, duct, lumen or tubular organ, the two filament sections **66A** and **66B** are retracted. As will be described later, to draw the collar **332** of the connector assembly **332** back through the opening **14** in the wall of the vessel, duct, lumen or tubular organ. Continued retraction of the filament sections cause the top or proximal surface of the anchor member **326** to engage the interior surface of the vessel, duct, lumen or tubular organ contiguous with the opening **14** to cause it to hang-up in the same manner as described earlier. Once the anchor hangs-up, continued retraction of the filament section cause the corrugated tube **324** to stretch or straighten out, thereby increasing the length of the tube from the state shown in FIG. **5** to the state shown in FIG. **6**. Once the connector assembly **322** is in the fully deployed state shown in FIG. **6**, the second connector member **64** and the bypass graft **10** connected to it can be secured to the assembly **322** in the same manner as described heretofore.

Referring now to FIGS. **1** and **12**, the details of the deployment instrument **24** will now be described. Thus, as can be seen the deployment instrument **24** basically comprises the heretofore identified carrier tube **82** and the heretofore described pusher-guide assembly. That assembly includes the pusher-guide member **86** and an actuation assembly **110**.

The carrier tube **84** includes an annular ring or stop **112** secured about its outer periphery immediately adjacent the proximal end **114**. The stop **112** is provided to ensure that the carrier tube of the deployment instrument is not extended too far into the introducer sheath **28**. Thus, the stop is arranged to engage the rear wall **38** of the hemostasis valve when it is in proper position.

The proximal end **114** of the guide tube is in the form of an inwardly extending, annular wall **116** having a central passageway **118** therein. The passageway **118** is adapted to closely receive the outer surface of the cylindrical portion of the pusher-guide member **86** to form a generally fluid-tight seal therebetween. The proximal end **120** of the pusher-guide member **86** is in the form of an inwardly extending annular wall **122** having a central passageway **124** therein. The central passageway **124** is arranged to closely receive a portion of the actuation assembly **110** (to be described hereinafter) to form a generally fluid tight seal therebetween.

The actuation assembly **110** basically comprises an elongated cylindrical mandrel rod **126** having a central passageway **128** extending along its length between its open distal end **130** and its open proximal end **132**. The passageway **128** communicates with the interior of the pusher-guide member **86**. An actuation cap **134** is mounted on the proximal end of the mandrel rod, with a helical compression spring **136** extends about the outer periphery of the hollow mandrel rod **126** interposed between the proximal end **120** of the pusher-guide tube **86** and a stop surface **138** forming the distal end of the actuation cap **134**. The cap **134** basically comprises a pair of hollow tubular sections **140** and **142**. The section **142** is disposed proximally of section **140** and is cup-shaped. The section **140** is fixedly secured to the mandrel rod **126** with the distal end of the filament section **66B** tightly interposed therebetween. In particular, filament sections **66A** and **66B** extend from the connector assembly **22** through the pusher-guide member **86** into the hollow interior of the mandrel rod **126** and out the proximal end opening **132** of the passageway **128** extending through the mandrel rod **126**. The distal end portion of filament **66B** extends under the cup-shaped cap section **142** and is trapped between the outer surface of the mandrel rod **126** and the inner surface of the cap shaped **140**. The distal end of the filament section **66A** also extends out the proximal end **132** of the passageway **128** and is trapped between the outer surface of the mandrel tube **128** and the inner surface of the cup-shaped portion **142** of the cap **134**. The cup-shaped portion **142** of the cap is removable for reasons to be described later.

The cap **134** also includes a central aperture in its end wall in communication with the interior passageway **128** of the mandrel tube **126**. A plug, formed of a resilient material, such as rubber, is releasably located within the aperture **144** to seal it. The aperture **144**, with the plug removed serves as a means to enable the deployment instrument **24** to determine the location of the wall of the vessel, duct, lumen or tubular organ as will be described later.

Operation of the deployment instrument **24** is as follows:

The instrument is inserted into the introducer sheath after the sheath has been positioned with the piercer-dilator to form the opening **14** in the wall of the vessel, duct, lumen or tubular organ and the piercer-dilator has been removed. To that end, the deployment instrument is extended through the introducer sheath which is positioned as shown in FIG. **7** until the stop ring **112** on the deployment instrument **24** abuts the proximal end **38** of the hemostasis valve of the introducer sheath **28**, as shown in FIG. **8**. The cap **134** of the actuation assembly **110** is then pushed in the distal direction, thereby imparting movement in the distal direction to the pusher-guide tube **86** via the interposed spring **136**. This action causes the free distal end **90** of the guide-pusher member to engage the proximal end of the anchor member **64** of the connector assembly **22** within the carrier tube **82**. Continued pushing on the cap in the distal direction causes the pusher-guide member to eject the first connector member **60** and the anchor member **62** as described heretofore. Once the connector assembly's components are free of the guide tube and are located within the interior of the vessel, duct, lumen or tubular organ, the spring in attempting to assume its uncompressed natural state, applies tension to the filament sections **66A** and **66B**. In particular, the release of pressure on the cap **136** allows the spring to move from its compressed state shown in FIG. **1** to a longitudinally expanded or uncompressed state shown in FIG. **12**. Since the filament ends are trapped by the cap **134**, this action pulls the filament sections in the proximal direction, thereby drawing the components **60** and **62** of the first connector assembly **22**

into the deployed state shown in FIGS. 9 and 10. Once the components are in this state, the introducer sheath is withdrawn, i.e., pulled off the instrument, leaving the deployment instrument 24 in the position shown in FIG. 12.

The second connector member 64 with the bypass graft 10 secured thereto is then threaded and slid down the instrument 24 over the actuation assembly and the pusher-guide tube to the position shown in FIG. 12. If a hemostatic washer 108 is used, as is preferable, that washer is threaded on the deployment instrument in advance of the second connector member 64.

When the second connector member 64 and the associated bypass graft 10 are slid in a distal direction until the flange 92 either directly engages the anchor surface of the wall of the vessel, duct, lumen or tubular organ or indirectly engages it via an interposed hemostatic washer 108. One of the chamfered detents of the second connector member 64 will be engaged by chamfered detent 76 of the first connector member 60 to secure the first and second connector members together.

Once the connector members 60 and 62 are connected together, the deployment instrument 24 can be removed to leave the anastomotic connection in position. To that end, the cup-shaped portion 142 of the actuating cap 134 is removed, thereby freeing the proximal end of filament section 66A. The remaining portion 142 of the cap 146 is then pulled or withdrawn in the proximal direction to withdraw the deployment instrument from within the interior of the bypass graft 10. Since the proximal end of filament section 66A is no longer trapped but the proximal end of the filament section 66B is trapped by the cap section 140 retraction of the instrument 24 causes the filament section 66A to move down the passageway 128 of the mandrel tube. Eventually, the free end of section 66A will pass through the aperture 80 in the first connector member 60 and from there will be pulled through the passageway 72 of that member and through the bypass graft interior until it exits the proximal end of the graft. At this point, the deployment instrument 24 will be fully removed from the anastomotic connection, leaving that connection in the state shown in FIG. 14.

The proximal end (not shown) of the bypass graft 10 can be secured to the occluded coronary artery (not shown) distally of the occlusion by any suitable technique. For example, the distal end of the bypass graft can be surgically connected to the coronary artery, or it can be connected utilizing means similar to that described herein introduced via an access port or slit (not shown) made in the wall of the bypass graft or by means such as taught in our co-pending U.S. patent application identified above.

As mentioned earlier, the actuation cap 134 of the deployment instrument 24 includes an aperture 144 which is sealed with a plug 146. The aperture 144 enables one to determine if the deployment instrument is properly positioned with respect to the wall of the vessel, duct, lumen or tubular organ. This action is accomplished by removing the plug 146 from the aperture so if the instrument is disposed at the desired position it will be in communication with the interior of the vessel, duct, lumen or tubular organ. Accordingly, blood will be enabled to flow from the interior of the vessel, duct, lumen or tubular organ and through the hollow interior of the pusher-guide member, and the communicating passageway in the mandrel tube where it exits the proximal end of that passageway and through communicating port 144. Thus, when a drop of blood or other fluid appears at the port, the user of the instrument 24 knows that the device is in the

desired position. The plug 146 can then be reinserted into the aperture 144 to seal it so that no further blood can gain egress through the instrument 24.

It should be pointed out at this juncture that the piercer-dilator instrument 26 may be constructed to utilize a similar flashback construction to provide an indication of proper placement, by the egress of a drop of blood from the proximal end of the piercer-dilator. More likely, the formation of the opening in the wall of the vessel, duct, lumen or tubular organ will be preformed under direct vision. If a fluid flashback system is incorporated into piercer-dilator, or the introducer sheath, it will allow placement of the introducer sheath at a specific location within the vessel, duct, lumen or tubular organ without the need for direct observation.

It must be pointed out at this juncture that it is contemplated that the connector assemblies of this invention could be actively assembled or deployed by manual pulling of the filament sections and pushing on the pusher member instead of using a spring loaded system like described heretofore.

The bypass graft 10 is prepared by inserting the proximal end of the second connector member 64 into the open distal end of the graft section 10. The connector is held in place by use of one or more stainless steel spring clips 106. The spring clips and the second connector 64 are preferably available in different sizes to cater to different graft sizes. In particular, the spring clips 106 are sized to a predetermined inside diameter to limit the constriction of the graft which would otherwise cause necrosis of the interposed tissue due to excessive pressure. Other means can be utilized to secure the graft 10 to the second connector member 64. Such means may be a biocompatible adhesive, pre-knotted suture loops, sutures, c-clips, etc.

The inside profile of the passageways of the connector assemblies of this invention are preferably designed to minimize turbulence and control the pressure of fluid flowing therethrough, such as disclosed in our heretofore identified co-pending patent application. It should also be pointed out that the various connector components of the connector assemblies of this invention can be coated with, or impregnated with chemicals, drugs, or other biologically active components to affect the nearby tissue or cells. Such active components could include, but are not limited to, anti-platelet drugs, antimicrobial agents, antibiotics, anti-thrombogenic materials, anti-oxidants, growth factors, growth hormones, genetic material, or seeded cells.

It should be noted that the embodiments of the connector assemblies and/or the deployment instrument and/or the piercer-dilator instrument, and/or the introducer sheath as shown and described heretofore are merely exemplary. Thus, other constructions are contemplated. For example, the anchor member may be shaped other than a linear strip, e.g., it may be slightly arcuate or trough-shaped like that disclosed in our aforementioned copending application. The positioning member for the connector assemblies may comprise other types of components making use of at least one filament or may comprise other devices, such as a flexible wire having a balloon on its distal end. The connector assemblies and/or the components thereof need not be formed to be totally resorbable. Thus, none or only portions of such assemblies may be resorbable.

In FIG. 15 there is shown by means of an illustration the anterior side of a human heart 2 which has had two occluded coronary arteries, namely, the left anterior descending 4 and the circumflex 6, bypassed by a bifurcated bypass graft composed of three graft sections 10A, 10B and 10C (to be described later) using an anastomosis connection system 200

constructed in accordance with one aspect of this invention. The system **200** basically comprises an upstream anastomosis connector **202**, a pair of downstream anastomosis connectors **204** and **206** and an intermediate or midstream bifurcated anastomosis connector **208**, so that both coronary arteries can be bypassed from a common, single connection point at the aorta.

It should be pointed out at this junction that the system **200** may be used to bypass more than two coronary arteries via a single common connection to the aorta using the teachings of this invention. Thus, for example, the intermediate or midstream connector may be trifurcated, i.e., have one input passageway or port and three output passageways or ports communicating with the input passageway. That trifurcated anastomosis connector may be used to connect three bypass graft sections to the common, single connection point at the aorta, and with the downstream ends of the three bypass graft sections being connected to respective coronary arteries downstream of the occlusions therein. Other anastomosis connectors for connecting more than three bypass graft sections to a common aortic connection point may be provided in accordance with this invention.

Irrespective of how many bypass graft sections are to be connected to the common junction with the aorta, it is preferred that all of the anastomosis connectors used to achieve that end be formed of a resorbable material, like that described heretofore, although it is contemplated that some or all of the connectors of the system may be formed of non-resorbable, biocompatible materials depending upon the application desired. The upstream and downstream anastomosis connectors are preferably constructed in accordance with the teachings of either the '582 or '684 applications, although they can be of different constructions as well, depending upon the desires of the surgeon and the particular anatomical structures to be encountered.

Turning now to the exemplary embodiment of the anastomosis connector system shown in FIG. **15**, it can be seen that the proximal tubular portion **202A** of the upstream anastomosis connector **202** extends out of the opening (not shown) in the aorta through which it was placed. This outwardly extending portion may be linear, curved, angled, elbowed, etc., and may extend perpendicularly to the longitudinal axis of the aorta, or at some angle to it. In the embodiment shown the outwardly extending portion **202A** is in the form of a right-angle elbow which includes a linear portion extending perpendicularly to the longitudinal axis of the aorta, and a free end extending parallel to that longitudinal axis. It is the free end of the portion **202A** to which the bypass graft section **10A** is connected. That graft section is similar to the grafts described heretofore. Moreover, the proximal end of the graft section **10A** is connected to the free end of the anastomosis connector portion **202A** via a snap-connector (like that disclosed earlier, e.g., connector **64**) fixedly secured to the proximal end of the graft section **10A**. A hemostatic, e.g., collagen, ring **210** may be provided extending about the periphery of the anastomosis connector portion **202A** where it extends out of the opening in the aorta to prevent the leakage of blood at that interface. Alternatively, an adhesive or some other flowable or settable material may be used at this location to seal that interface.

The distal end of the graft section **10A** is connected via a similar snap-connector to the inlet passageway or port (to be described later) of the bifurcated anastomosis connector **208**. The two other bypass graft sections **10B** and **10C** are connected to the two outlet passageways or ports (also to be described later) of the bifurcated anastomosis connector **208**, via respective snap-connectors located at their respec-

tive proximal ends. The distal ends of the bypass graft sections **10B** and **10C** are connected via respective snap-connectors to the downstream anastomosis connectors **204** and **206**, respectively. These downstream anastomosis connectors **204** and **206** are constructed similarly to the upstream connector **202**, except that as shown the outwardly extending tubular portion **204A** of the downstream connector **204** is not in the form of an elbow. Rather it is linear in shape so that it extends perpendicularly to the longitudinal axis of the left anterior descending artery **4** downstream of the occlusion therein. The other downstream anastomosis connector **206** does include a tubular elbow shaped extending portion **206A**, and that portion extends out of the opening in the wall of the circumflex artery **6** downstream of the occlusion therein.

It should be noted that the choice of shape of the outwardly extending portions of the upstream and/or downstream anastomosis connector will be left up to the surgeon based on his/her desires and the anatomical structures involved.

If desired, a hemostatic ring or an adhesive, glue or some other flowable, settable material may be used at the interface of either of the downstream anastomosis connectors and the opening in the wall of the artery through which they extend to effect the sealing of that interface.

As can be seen in FIG. **15**, the bifurcated midstream anastomosis connector **208** comprises a generally Y-shaped hollow member having an input port **208A** through which a central passageway (not shown) extends, and a pair of output ports **208B** and **208C**. Each of these ports includes a central passageway (not shown) extending therethrough. The three passageways are in fluid communication with one another at a smooth walled internal junction to minimize blood turbulence therein. Moreover, the cross sectional area of each of the passageways may be sized and shaped to further minimize blood turbulence. Thus, blood entering into the input port's passageway from the aortic connection will branch off and flow into each of the output passageways of the bifurcated anastomosis connector for passage via their respective ports and associated bypass graft sections to the respective coronary arteries to which the bypass graft sections are connected.

The deployment of the upstream anastomosis connectors may be accomplished in any manner desired in accordance with the teaching of this application or the '582 or '684 applications. Thus, for example, if the upstream (aortic) anastomosis connector **202** is constructed like the heretofore described anastomosis connector **22** it may be deployed by use of the instrument **24** in a similar manner to that described above. The bypass graft section **10A** with a snap-connector **62** on its proximal end can then be snap-connected to the outwardly extending tubular portion **202A** of the upstream anastomosis connector **202** using that instrument and in the same manner as described above. Each of the downstream anastomosis connectors **204** and **206** can be similarly constructed to the upstream connector **202** and deployed in their respective coronary arteries **4** and **6** downstream of the occlusions in a similar manner. Once deployed the bypass graft section **10B** with a snap-connector **62** on its proximal end can then be snap-connected to the outwardly extending tubular portion **204A** of the downstream anastomosis connector **204** in the same manner as described above. Similarly, the bypass graft section **10C** with the snap-connector **62** on its proximal end can be snap-connected to the outwardly extending tubular portion **206A** of the downstream anastomosis connector **206**.

Once all of the bypass graft sections **10A-10C** have been connected to their respective native arteries they can be

connected to one another via the midstream bifurcated anastomosis connector **208**. To that end the distal end of the bypass graft section **10A** having a snap-connector **62** fixedly secured thereto can be snap-connected to a mating portion (not shown) constructed like detent **76** on the upstream port of the bifurcated anastomosis connector **208**. The proximal end of the bypass graft section **10B** having a snap-connector **62** fixedly secured thereto can be snap-connected to a mating portion (not shown) constructed like detent **76** on one of the downstream ports of the bifurcated anastomosis connector **208**. In a similar manner the proximal end of the bypass graft section **10C** having a snap-connector **62** fixedly secured thereto can be snap-connected to a mating portion (not shown) constructed like detent **76** on the other of the downstream ports of the bifurcated anastomosis connector **208**. This completes the assembly of the bypass graft system to enable blood to flow from the aorta around the occluded coronary arteries to points downstream of the occlusions therein.

Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

We claim:

1. A system for effecting the bypass of portions of at least two native blood vessels from an upstream blood vessel within the body of a living being by use of at least two bypass grafts, the native blood vessels and the upstream blood vessel each having a wall with an opening provided therein, said system comprising a first upstream anastomosis connector for connection to a upstream blood vessel, at least two downstream anastomosis connectors for connecting the at least two bypass grafts to respective ones of the at least two native blood vessels, said upstream connector including an internal portion arranged to be extended through the opening in the upstream blood vessel for communication with the interior of the upstream blood vessel and an external portion arranged to extend outside the upstream blood vessel, said downstream connectors each including an internal portion arranged to be extended through the opening in a respective downstream blood vessel for communication with the interior of the respective downstream blood vessel and a external portion arranged to extend outside the respective downstream blood vessel, said anastomosis connectors being arranged to be coupled together to establish a path for carrying blood through said anastomosis connectors from the upstream blood vessel through the at least two bypass grafts to the respective downstream blood vessels.

2. The system of claim **1** wherein said system comprises a midstream anastomosis connector having an inlet port and at least two outlet ports, said inlet port being arranged to be coupled to said external portion of said upstream connector, said outlet ports being arranged to be coupled to respective ones of the bypass grafts.

3. The system of claim **2** wherein each of the at least two bypass grafts includes an upstream end and a downstream end, and wherein said downstream connectors are arranged to be fixedly secured to respective ones of the downstream ends of the at least two bypass grafts.

4. The system of claim **3** wherein one of said outlet ports of said midstream connector is arranged to be fixedly secured to the upstream end of one of the at least two bypass grafts, and the other of said outlet ports of said midstream connector is arranged to be fixedly secured to the upstream end of the other of the at least two bypass grafts.

5. The system of claim **4** wherein said fixed securement between the upstream ends of the at least two bypass grafts

and the midstream connector is accomplished by snap-action means connection means.

6. The system of claim **5** wherein said fixed securement between the downstream ends of the at least two bypass grafts and the downstream connector is accomplished by snap-action connection means.

7. The system of claim **1** wherein at least a portion of at least one of said anastomosis connectors is formed of a resorbable material.

8. The system of claim **1** additionally comprising a removable deployment instrument for introducing at least a portion of said upstream connector into the upstream blood vessel through the opening in the wall thereof.

9. The system of claim **1** additionally comprising a removable deployment instrument for introducing at least a portion of each of said downstream connectors into respective ones of the downstream blood vessels through respective openings in the walls thereof.

10. The system of claim **8** additionally comprising a removable deployment instrument for introducing at least a portion of each of said downstream connectors into respective ones of the downstream blood vessels through respective openings in the walls thereof.

11. The system of claim **1** wherein said upstream connector and said intermediate connector are arranged to be coupled together by another bypass graft, the other bypass graft having an upstream end and a downstream end, wherein said external portion of said upstream connector includes means for fixedly securing it to the upstream end of the other bypass graft, and wherein midstream connector includes means for fixedly securing it to the downstream end of the other by pass graft.

12. The system of claim **11** wherein said means for fixedly securing the upstream end of the other bypass graft and to external portion of the upstream connector comprises snap-action connection means, and wherein said means for fixedly securing the downstream end of the other bypass graft to the midstream connector comprises snap action connection means.

13. The system of claim **1** wherein each of the blood vessels has a longitudinal axis adjacent the opening therein and wherein said external portion of at least one of said connectors includes a first portion which extends at an angle to the longitudinal axis.

14. The system of claim **13** wherein said angle is approximately 90 degrees.

15. The system of claim **14** wherein said external portion of at least one of said connectors includes a second portion extending generally parallel to the longitudinal axis.

16. The system of claim **1** wherein said midstream connector is a generally Y-shaped member.

17. The system of claim **1** additionally comprising sealing means for forming a hemostatic seal at the interface of at least one of said connectors and the blood vessel to which it is secured.

18. The system of claim **17** wherein said sealing means comprises a collagen sleeve arranged to be disposed about a portion of said external portion of said at least one of said connectors.

19. The system of claim **1** wherein said external portion of said upstream connector comprises a tubular section.

20. The system of claim **1** wherein said external portion of each of said downstream connectors comprises a tubular section.

21. The system of claim **19** wherein said upstream connector is arranged to be fixedly secured to a bypass graft, the bypass graft including an upstream end and a downstream

19

end, said tubular section of said upstream connector being arranged to be disposed within the upstream end of the bypass graft.

22. The system of claim 20 wherein each of said downstream connectors is arranged to be fixedly secured to a respective one of the at least two bypass grafts, with each of the at least two bypass grafts including an upstream end and a downstream end, said tubular section of a first of said downstream connectors being arranged to be disposed within the downstream end of a first of the at least two bypass grafts, and said tubular section of a second of said at least two downstream connectors being arranged to be disposed within the downstream end of a second of the at least two bypass grafts.

23. The system of claim 21 additionally comprising binding means to encircle a portion of the upstream end of the bypass graft to the tubular portion of the upstream connector to enhance the securement of the bypass graft thereto.

24. The system of claim 21 additionally comprising binding means to encircle a portion of the downstream end of each of the at least two bypass graft to the respective tubular portions of the downstream connectors to enhance the securement of the bypass grafts thereto.

25. The system of claim 1 wherein each of the at least two bypass grafts includes an upstream end and a downstream end, and wherein said system comprises a first connector member and a second connector member, said first connector member being fixedly secured to the downstream end of a first of said at least two bypass grafts, said second connector member being fixedly secured to the downstream end of a second of said at least two bypass grafts, said first connector member being arranged to be secured to said external portion of at least one of said downstream connectors, said second connector member being arranged to be secured to said external portion of at least another of said downstream connectors.

26. The system of claim 25 wherein said first connector member is arranged to be snap-connected to said external portion of at least one of said downstream connectors, and wherein said second connector member is arranged to be snap-connected to said external portion of at least another of said downstream connectors.

20

27. The system of claim 2 wherein each of the at least two bypass grafts includes an upstream end and a downstream end, and wherein said system comprises a first connector member and a second connector member, said first connector member being fixedly secured to the upstream end of a first of said at least two bypass grafts, said second connector member being fixedly secured to the upstream end of a second of said at least two bypass grafts, said first connector member being arranged to be secured to one of said outlet ports of said intermediate connector, said second connector member being arranged to be secured to another of said outlet ports of said intermediate connector.

28. The system of claim 27 wherein said fixed securement of said first connector member to one of said outlet ports is accomplished by a snap-connection, and wherein said securement of said second connector member to another of said outlet ports is accomplished by a snap-connection.

29. The system of claim 26 wherein said system comprises a midstream anastomosis connector having an inlet port and at least two outlet ports, said inlet port being arranged to be coupled to said external portion of said upstream connector, said outlet ports being arranged to be coupled to respective ones of the bypass grafts.

30. The system of claim 29 wherein said system comprises a third connector member and a fourth connector member, said third connector member being fixedly secured to the upstream end of a first of said at least two bypass grafts, said fourth connector member being fixedly secured to the upstream end of a second of said at least two bypass grafts, said third connector member being arranged to be secured to one of said outlet ports of said intermediate connector, said fourth connector member being arranged to be secured to another of said outlet ports of said intermediate connector.

31. The system of claim 30 wherein said fixed securement of said third connector member to one of said outlet ports is accomplished by a snap-connection, and wherein said securement of said fourth connector member to another of said outlet ports is accomplished by a snap-connection.

* * * * *